

Interview Summary	Application No.	Applicant(s)	
	10/600,298	NIKOLCHEV ET AL.	
	Examiner	Art Unit	
	Michael Brown	3772	

All participants (applicant, applicant's representative, PTO personnel):

(1) Michael Brown.

(3) Jim Conley.

(2) Howard Wisnia.

(4) Patricia Bianco, Henry Bennett, J. Harrison.

Date of Interview: 19 October 2006.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.
If Yes, brief description: Product demonstration.

Claim(s) discussed: 12-81 and proposed suggested claims.

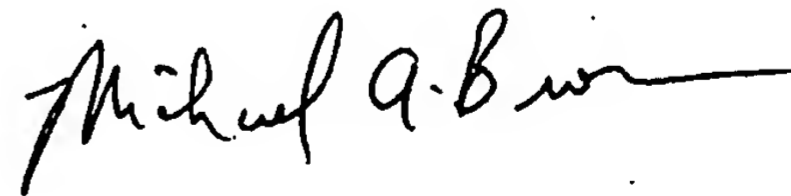
Identification of prior art discussed: Art of record.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: An agreement was made that claims 35-37 are supported by the 95 filing, Claims 22-34 and 34-81 will be cancelled. An agreement was made for proposed alternative claims 1, 3 and 5 to be submitted and are supported by the 95 filing. Discussion of potential interference was also discussed.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.



MICHAEL A. BROWN
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

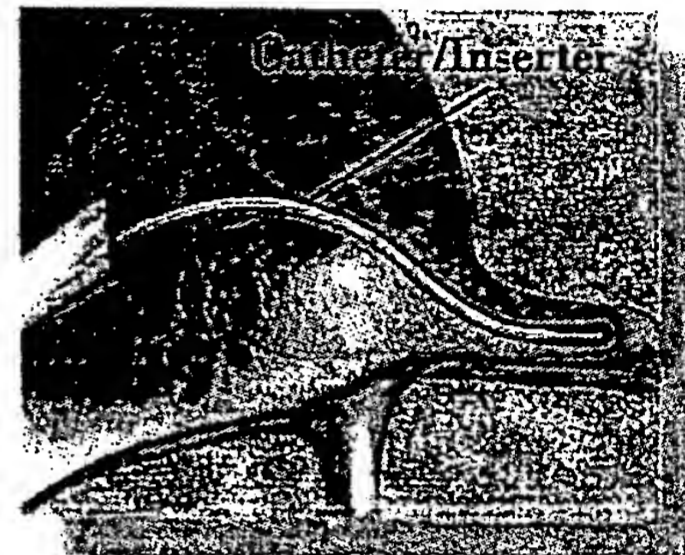
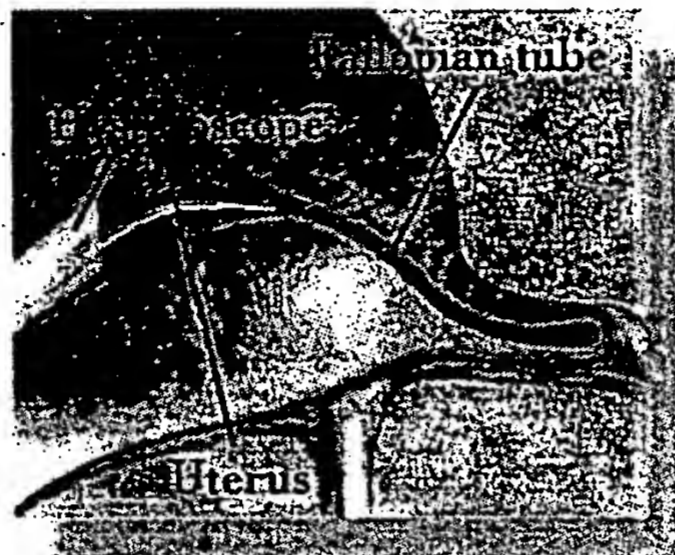
Examiner's signature, if required

APP. S/N 10/600,298

October 19, 2006
Interview Materials

Conceptus Device

How is the Essure™ procedure performed?



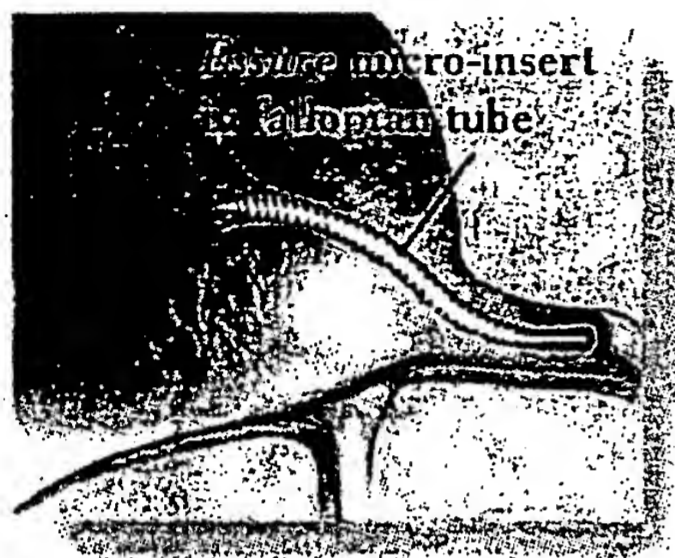
One to 2 hours before the procedure, you are given medication to reduce tubal spasms and uterine cramping during the procedure.

Step 1

After a local anesthetic is injected into or applied to the cervix, the doctor inserts a narrow telescope, called a hysteroscope, through your vagina and cervix (the entrance to the uterus from the vagina) and into the uterus. The doctor may need to gently expand the opening of your cervix and may insert an instrument to do this. The hysteroscope is attached to a video camera and monitor so the doctor is able to see exactly what he or she is doing. Fluid, called normal saline (salt water), flows through the hysteroscope and into your uterus. The fluid is used to expand the uterus so the doctor can see the openings to your fallopian tubes. You might feel cramping from this.

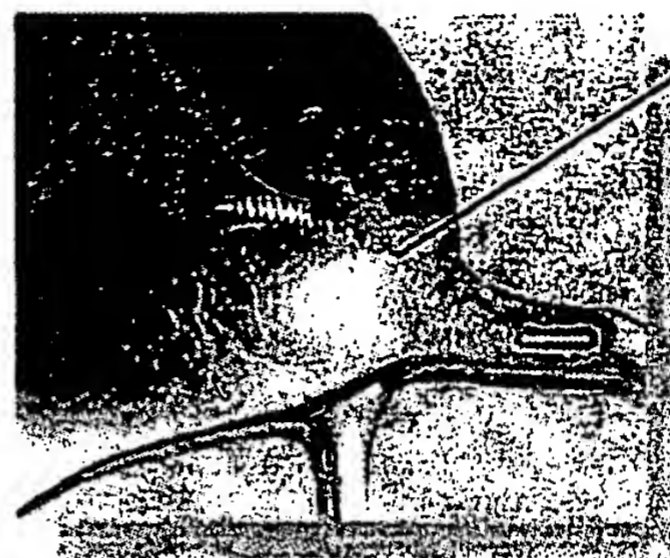
Step 2

A narrow inserter, called a catheter, is passed through the hysteroscope and into your fallopian tube. The micro-insert is attached to the end of the inserter.



Step 3

The micro-insert is placed in the fallopian tube and the inserter is removed. The process is repeated in the other fallopian tube. The entire procedure should take about 35 minutes, with only 15 minutes typically required to place the micro-inserts into the fallopian tubes.



Step 4

During the next 3 months, tissue will begin to grow into the micro-inserts, eventually blocking your fallopian tubes. You will need to use another form of birth control during this period until your doctor confirms that the procedure has worked.

After 3 months, you need to have a test called a hysterosalpingogram (HSG). This test is required before your doctor can tell you whether you may begin relying on *Essure* for contraception. During an HSG, your doctor fills your uterus with dye and then takes an X ray to see if the dye remained in your uterus or traveled down your fallopian tubes. The purpose of this test is to make sure that both of your tubes are blocked and that both of the micro-inserts are in the correct position.

Note: Always call your doctor if you have any unusual pain, bleeding, or other symptoms.

Micro-insert Design

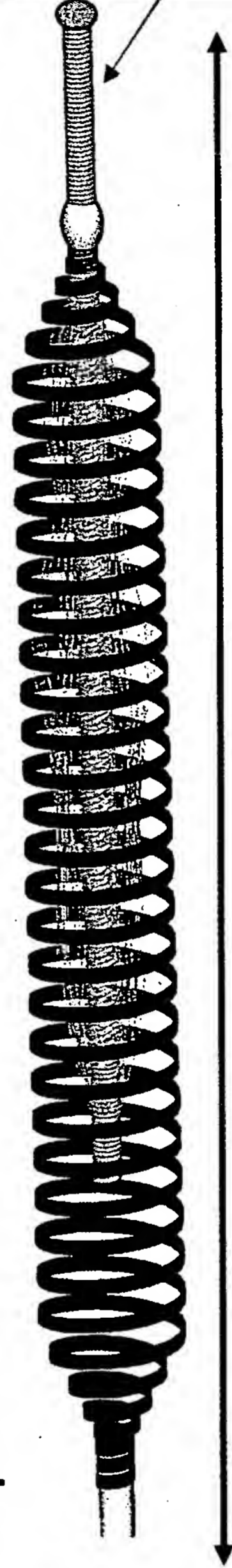
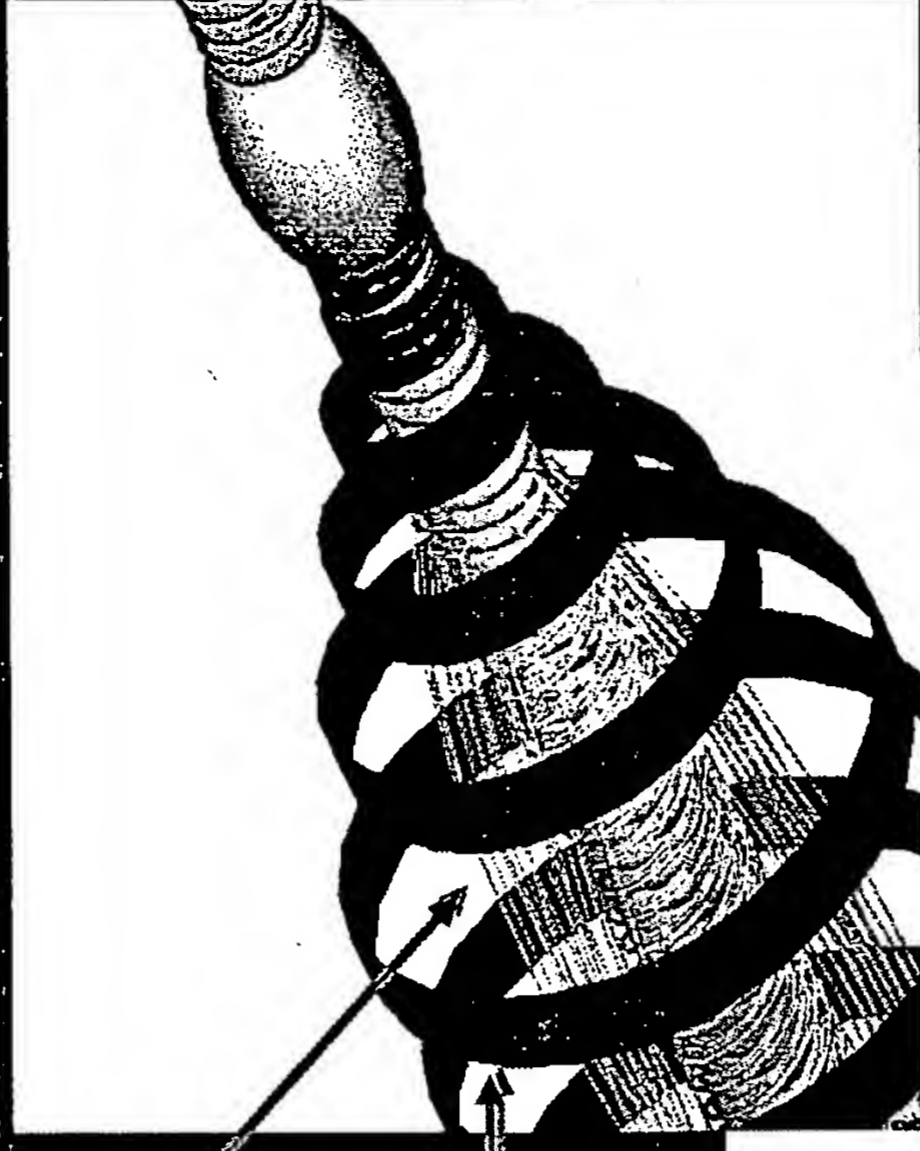
Fiber Material:
PET

Dynamic Expanding
Superelastic Outer Coil
Material: Nitinol

Wound Down Diameter 0.8 mm
Expanded Diameter 1.5 – 2.0 mm

Inner Coil
Material:
Stainless
Steel

Micro-insert Length = 4 cm



Family Trees

Conceptus Application Family Tree

Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
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6/7/1995

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6/7/1995

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9/8/1995

2/11/1997
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9/24/1997
(provisional)

(fully supports
835 app--has
the exact
same spec
and drawings)

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1/23/2001
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[illegible]

[illegible]

CON '240 Patent
(1995)



US006176240B1

(12) **United States Patent**
Nikolchev et al.

(10) Patent No.: **US 6,176,240 B1**
(45) Date of Patent: **Jan. 23, 2001**

(54) **CONTRACEPTIVE TRANSCERVICAL
FALLOPIAN TUBE OCCLUSION DEVICES
AND THEIR DELIVERY**

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(73) Assignee: **Conceptus, Inc., San Carlos, CA (US)**

(*) Notice: Under 35 U.S.C. 154(b), the term of this
patent shall be extended for 0 days.

(21) Appl. No.: **08/474,779**

(22) Filed: **Jun. 7, 1995**

(51) Int. Cl.⁷ **A61F 6/06**

(52) U.S. Cl. **128/830; 128/831**

(58) Field of Search **128/830-841**

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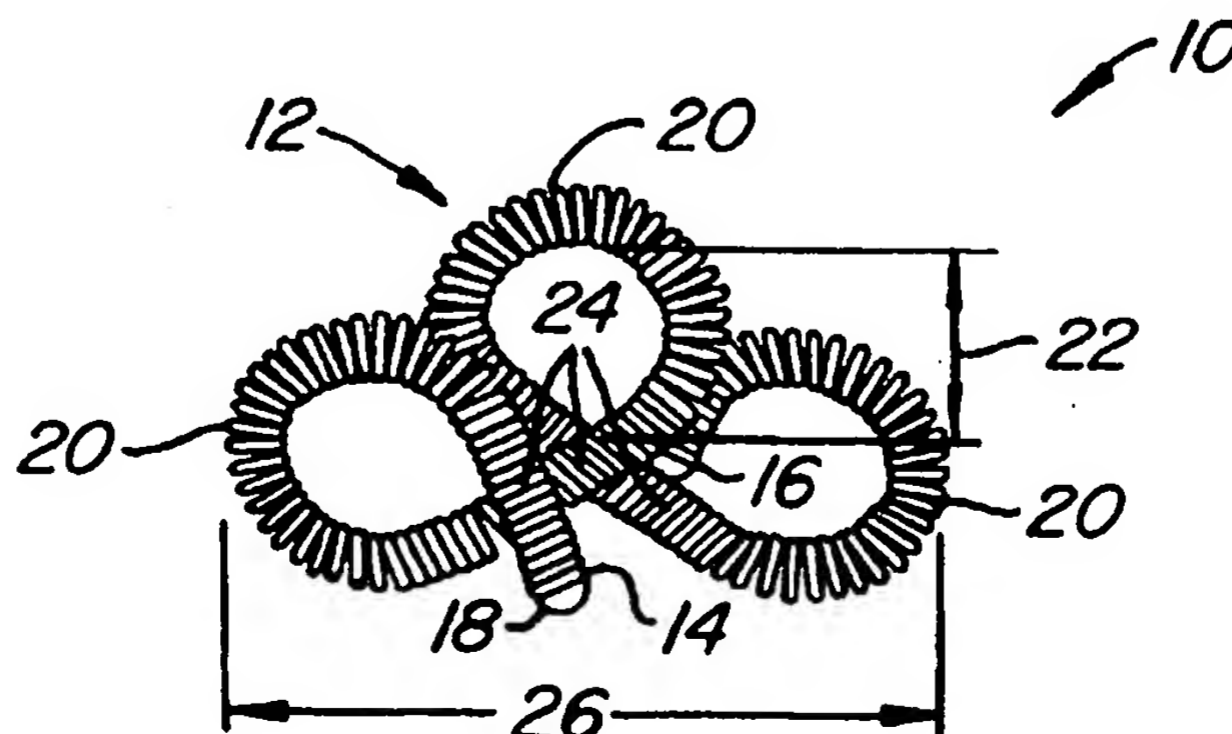
Primary Examiner—Michael A. Brown

(74) *Attorney, Agent, or Firm*—Townsend Townsend & Crew LLP

(57) **ABSTRACT**

The invention provides intrafallopian devices and non-surgical methods for their placement to prevent conception. The efficacy of the device is enhanced by forming the structure at least in part from copper or a copper alloy. The device is anchored within the fallopian tube by imposing a secondary shape on a resilient structure, the secondary shape having a larger cross-section than the fallopian tube. The resilient structure is restrained in a straight configuration and transcervically inserted within the fallopian tube, where it is released. The resilient structure is then restrained by the walls of the fallopian tube, imposing anchoring forces as it tries to resume the secondary shape.

38 Claims, 4 Drawing Sheets-



CON '240 APP
(1995)

PATENT APPLICATION

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN
TUBE OCCLUSION DEVICES AND THEIR DELIVERY

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CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND THEIR DELIVERY

BACKGROUND OF THE INVENTION

1. Field of the Invention

10 The present invention relates generally to
contraception, and more particularly to intrafallopian
contraceptive devices and nonsurgical methods for their
delivery.

15 Worldwide demand exists for safe, effective methods
of both contraception and permanent sterilization. Although a
variety of contraception and sterilization methods are
available, all of the existing methods have limitations and
disadvantages. Thus, the need for additional safe, low cost,
reliable methods of contraception and permanent sterilization,
both in developed and less developed countries, is widely
20 recognized.

Many presently available contraception methods
require significant user involvement, and user non-compliance
results in quite high rates of failure. While the theoretical
effectiveness of existing contraceptives, including barrier
25 methods and hormonal therapies, is well established,
overcoming user noncompliance to improve overall efficacy has
proven difficult.

One form of contraception which is less susceptible
to user noncompliance is the intrauterine device (IUD). IUDs
30 have been found to have higher rates of reliability, and are
effective for a longer period of time, than most other
commercially available contraceptives. Unfortunately, IUDs
are also associated with serious infectious complications.
For this reason, the use of IUDs within the United States has
35 decreased dramatically. Additionally, IUDs are subject to
unplanned expulsion, and must be removed due to excessive pain
or bleeding in a percentage of cases, further reducing the
acceptance of the IUD as a contraceptive method.

Interestingly, the efficacy of copper IUDs appears to be higher than that of non-metallic IUDs. The reason for this has not been fully explained.

Commercially available options for permanent sterilization include fallopian tube ligation and vasectomy. These methods are surgical, are difficult to reverse, and are not available to many people in the world. It is common knowledge that fertilization occurs in the fallopian tubes where the sperm and ovum meet. Tubal ligation avoids this by complete occlusion of the fallopian tubes.

It has previously been proposed to reversibly occlude the fallopian tubes, for example, by *in vitro* formation of an elastomeric plug, or otherwise anchoring a device on either side of the narrowest region of fallopian tube, called the "isthmus." Such fallopian tube occlusion methods appear promising; however, an unacceptably high percentage of the non-surgical devices proposed to date have become dislodged during previous studies. Even where non-surgical intrafallopian devices have remained in place, they have been found to be only moderately effective at preventing conception.

For these reasons, it would be desirable to provide effective, reliable intrafallopian devices for contraception and sterilization. It would be particularly desirable to provide highly effective intrafallopian devices which did not require surgery for placement. It would be especially desirable if such devices and methods allowed easy placement of the device, but were less susceptible to being dislodged than previously proposed non-surgical intrafallopian devices.

2. Description of the Related Art

The experimental use of a stainless steel intrafallopian device is described in *Transcatheter Tubal Sterilization in Rabbits*, Penny L. Ross, RT 29 "Investigative Radiology", pp. 570-573 (1994). The experimental use of an electrolytically pure copper wire as a surgical contraceptive intrafallopian device in rats was described in "Antifertility Effect of an Intrafallopian Tubal Copper Device", D.N. Gupta,

14 *Indian Journal of Experimental Biology*, pp. 316-319 (May 1976).

U.K. Patent Application Pub. No. 2,211,095 describes a uterine screw plug for blocking the fallopian tube.

5 European Patent Application Pub. No. 0,010,812 describes a device for placement in the oviducts having enlargements at either end for anchoring the device. The same device appears to be described in Netherlands Patent No. 7,810,696.

10 The use of tubal occlusion devices is described in "Hysteroscopic Oviduct Blocking With Formed-in-Place Silicone Rubber Plugs", Robert A. Erb, Ph.D., et al., *The Journal of Reproductive Medicine*, pp. 65-68 (August 1979). A formed-in-place elastomeric tubal occlusion device is described in U.S. Patent No. 3,805,767, issued to Erb. U.S. Patent No. 5,065,751, issued to Wolf, describes a method and apparatus for reversibly occluding a biological tube. U.S. Patent No. 4,612,924, issued to Cimber, describes an intrauterine contraceptive device which seals the mouths of the fallopian tubes.

20 German Patent No. 28 03 685, issued to Brundin, describes a device for plugging a body duct with a device which swells when in contact with a body fluid.

Alternative contraceptive devices are disclosed in copending U.S. Patent Application Serial No. _____ (attorney docket no. 16355-25), the full disclosure of which is herein incorporated by reference.

SUMMARY OF THE INVENTION

30 The present invention provides intrafallopian devices and methods for their placement to prevent conception. The intrafallopian devices of the present invention are transcervically delivered, resiliently anchored structures which are formed at least in part from copper to provide long term contraception, or alternatively permanent sterilization, without the need for surgical procedures or the increased bleeding, pain, and risks of infection associated with intrauterine devices (IUDs).

The use of copper in the intrafallopian device of the present invention improves its efficacy as a contraceptive method. Devices formed from plastically deformable materials, however, are less readily restrained in the fallopian tube.

5 Apparently, the large variation in the actual shape and dimensions of fallopian tubes does not provide reliable anchoring for a pre-formed deformable intrafallopian device. The intrafallopian device of the present invention therefore comprises a resilient structure, usually a metallic coil,
10 which includes a copper alloy, a copper plating, or copper fibers, ideally comprising an alloy including at least 75% copper. The coil material typically includes beryllium, zinc, stainless steel, platinum, a shape memory alloy such as Nitinol[™], or the like. Preferably, the coil is composed of an
15 alloy of beryllium and copper. Although the present device will generally result in occlusion, it need not completely occlude the fallopian tube to prevent the meeting of the sperm and ovum. Instead, the presence of the copper on the resilient structure is sufficient to provide effective
20 contraception.

Conveniently, the present invention further comprises non-surgical placement of such intrafallopian devices by transcervical introduction. The resilient
structure is restrainable in a straight configuration, e.g.,
25 by inserting the device within a catheter, greatly facilitating and reducing the risks of introduction. Thus, the cost and dangers associated with existing surgical contraceptive and sterilization procedures are avoided.

In a first aspect, a contraceptive intrafallopian
30 device according to the present invention comprises a resilient structure having a proximal end and a distal end. The resilient structure comprises copper, and is biased to form at least one bend near the proximal end of the primary coil. Similarly, the resilient structure is also biased to
35 form at least one bend near its distal end. These proximal and distal bends define an isthmus-traversing region therebetween. Preferably, the isthmus-traversing region also

includes at least one bend, thereby helping to anchor the coil within the fallopian tube.

5 Generally, the resilient structure of the present intrafallopian device will be formed as a primary coil. To help restrain the coil within the fallopian tube, fibers are attached to some embodiments of the coil, the fibers optionally comprising a polyester material such as Rayon™, Dacron™, or the like. Alternatively, copper fibers may be used to increase the exposed copper surface area, the copper
10 fibers generally having a diameter on the order of .001 inches.

The bends of the present intrafallopian device are generally formed as a secondary shape imposed on a primary coil. The primary coil is most easily formed as a straight
15 cylindrical coil. The secondary shape will be imposed on the primary coil by bending, optionally heat treating the primary coil while bent. The individual bends may take a wide variety of forms, including sinusoidal curves, the individual loops of a continuous secondary coil, or the like. However, the secondary shape generally defines an overall width which is
20 larger than the fallopian tube, so that the tubal wall restrains the resilient structure when it is released.

Preferably, each of the bends of the present intrafallopian device forms a loop in the primary coil when in
25 a relaxed state. Ideally, the loops are separated by straight sections of coil. The alternating of loops with straight sections of coil forms a large diameter "flower coil," which provides a large relaxed overall width, and also features bends of tight radius, both of which promote retention.

30 Conveniently, the primary coil generally has a diameter less than that of the fallopian tube, and can be restrained in a straight configuration for placement within the fallopian tube, typically by inserting the primary coil within a delivery catheter.

35 In another aspect, a contraceptive intrafallopian device according to the present invention comprises a resilient primary coil having a primary coil diameter. The primary coil comprises copper, and forms a secondary shape

when in a relaxed state. The secondary shape defines a plurality of bends and an overall width which is larger than the primary coil diameter. Thus the primary coil can be easily anchored in a fallopian tube which is smaller in diameter than the secondary shape. Preferably, the present device reacts with a force sufficient to prevent axial movement of the device within the fallopian tube when restrained in a lumen having a diameter in the range between .5 mm and 3 mm. The actual anchoring force will depend on the shape of the coil and the modulus of elasticity of the material used.

In yet another aspect, a intrafallopian contraceptive delivery system according to the present invention comprises an elongate body in which the resilient primary coil described above is slidably disposed. A shaft is also slidably disposed within the elongate body and is located proximally of the primary coil. The distal end of the shaft includes a coil interface surface, while the elongate body restrains the primary coil in a straight configuration.

Preferably, a bend in the isthmus-traversing region of the present intrafallopian device, together with the proximal and distal anchor bends, restrains the resilient structure within the isthmus of the fallopian tube. The distal anchor is inserted into the ampulla, distal of the isthmus, while the proximal anchor is located in the ostium, proximal of the isthmus. Unintended movement of the device is further avoided by locating the isthmus-traversing region within the isthmus to resiliently impose anchoring forces against the tubal wall.

In a still further aspect, an intrafallopian contraceptive method according to the principles of the present invention comprises restraining a resilient structure in a straight configuration and transcervically inserting the resilient structure into a fallopian tube. The resilient structure is affixed within the isthmus by releasing a bent isthmus-traversing region. The bend of the isthmus-traversing region exerts a force against the wall of the fallopian tube, anchoring the device within the isthmus. Preferably, a distal

anchor on the resilient structure is released distally of the isthmus, and a proximal anchor is released proximally of the isthmus, the distal and proximal anchors generally formed from bends in the resilient structure. Optionally, an electric current is applied through the resilient structure to the fallopian tube, thereby effecting permanent sterilization.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a first embodiment of a contraceptive intrafallopian device according to the present invention having a single distal anchor loop, a single proximal anchor loop, and an isthmus-traversing region having a single loop for anchoring the device within the fallopian tube.

Fig. 2 illustrates an alternative embodiment of a contraceptive intrafallopian device according to the present invention having a plurality of loops which may act as proximal, distal, or lumen anchors.

Fig. 3 illustrates the distal portion of a delivery catheter for placement of a contraceptive intrafallopian device according to the present invention.

Fig. 4 illustrates the contraceptive intrafallopian device of Fig. 1 partially released from the delivery catheter of Fig. 3.

Figs. 5 and 6 illustrate a contraceptive method using an intrafallopian device according to the principles of the present invention.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENT

The present invention encompasses a contraceptive intrafallopian device which can alternatively be used as both a permanent and a reversible means of contraception. The present contraceptive methods and devices minimize the danger of non-use which has limited the efficacy of prior art contraceptive techniques. Moreover, the location of the present devices within the fallopian tubes provides a reduced risk of the infectious complications, increased bleeding, and pelvic pain associated with intrauterine devices (IUDs).

Furthermore, the location and the novel shape of the present intrafallopian device provides significant advantages over IUDs, which have been found to be susceptible to unplanned expulsion and removal due to excessive pain and bleeding. The present invention takes advantage of the increase in effectiveness associated with copper IUDs, providing a resilient structure including copper which may be transcervically positioned without the need for surgery.

Although the present contraceptive method may be included within a group of contraceptive techniques generally referred to as fallopian tube occlusion methods, the present invention does not necessarily rely solely on blocking the fallopian tube to prevent fertilization. Instead, contraception is apparently provided by disrupting of ovum transport, the process of fertilization, and/or cleavage of the ovum. While the effect that copper has on these processes is not fully understood, it does appear that copper intrafallopian devices offer potentially significant increases in effectiveness over intrafallopian devices formed of other materials. Optionally, the present invention further encompasses devices which promote tissue growth within the tube to induce tubal occlusion, further inhibiting conception.

The present invention is anchored within the isthmus of the fallopian tube, overcoming the unintended expulsion of the device and the resulting failure of the contraceptive method. Such intrafallopian device expulsion has been the single greatest factor limiting the efficacy of easily positioned intrafallopian contraceptive techniques.

The present intrafallopian devices are generally elongate resilient structures pre-formed into secondary shapes. These secondary shapes will bias the resilient structure so as to provide strong forces against the lumen wall of the fallopian tube. Clearly, the secondary shape must have a larger outer diameter than the inner diameter of the fallopian tube.

Conveniently, the present resilient structures are insertable into a catheter, the catheter wall restraining the resilient structure in a straight configuration. As the

resilient structure has an outer diameter when in the straight configuration which is less than the inner diameter of the fallopian tube, the catheter containing the present intrafallopian device is easily transcervically introduced. Moreover, the device is readily removed by snaring the resilient structure near the proximal end and pulling proximally on the resilient structure, thereby straightening the resilient structure and allowing it to be withdrawn without injuring the fallopian tube. Alternatively, an electrical current is applied to the device after it is at least partially releasing the fallopian tube, providing permanent sterilization.

Referring now to Fig. 1, a first embodiment of the present contraceptive intrafallopian device 10 is formed from a resilient primary coil 12. Primary coil 12 is most easily originally formed as a straight cylindrical coil or spring, preferably having an outer diameter in the range from .2 mm to 5 mm, and having a length in the range from 20 mm to 150 mm. Ideally, primary coil 12 has an outer diameter in the range from .4 mm to 2 mm and a length in the range from 30 mm to 70 mm. The straight primary coil may then be bent into a variety of secondary shapes.

The primary coil 12 of intrafallopian device 10 includes a proximal end 14 and a distal end 16. Between these ends, three loops 20 are formed, each having an inner diameter 22. Located between loops 20 are straight sections 24, which increase the overall cross-section of the intrafallopian device to an overall width 26. Preferably, inner diameter 22 is in the range from 2 mm to 10 mm, while overall width 26 is at least 6mm, ideally being in the range from 8 mm to 40 mm. Distal and proximal ends 14, 16 each include an atraumatic endcap 18 to prevent injury to the fallopian tube.

Preferably, primary coil 12 is formed from a beryllium copper alloy wire. Beryllium copper provides the resilience necessary to avoid expulsion of the device, and also provides the increased effectiveness of a copper contraceptive intrafallopian device. Alternatively, primary

coil 12 is formed from a resilient metal, such as stainless steel, platinum, a shape memory alloy, or the like. If such materials are used, primary coil 12 is preferably plated with copper or a copper alloy or otherwise has copper attached.

5 To further reduce the possibility of expulsion of intrafallopian device 10, fibers are optionally carried on primary coil 12. The fibers may be short individual fibers, or may alternatively be wound into primary coil 12. Preferably, the fibers comprise copper, thereby increasing the
10 total copper surface area. Such copper fibers are preferably bonded to primary coil 12 with solder, brazing, a polymeric adhesive, or the like. Alternatively, polyester fibers such as Dacron™, Rayon™, or the like, are bonded to the surface of primary coil 12 using a polymeric adhesive. The polyester
15 fibers promote increased tissue growth around the coil, thus further reducing the possibility of expulsion of the device from the fallopian tube.

A secondary shape has been superimposed on the primary coil to form intrafallopian device 10, the secondary
20 shape comprising loops 20 separated by straight sections 24. This secondary shape is herein referred to as a "flower coil." The flower coil shape is particularly advantageous in that outer diameter 26 is substantially larger than the primary coil diameter, while the individual loops 20 have relatively
25 small inner diameters 22 which will maintain the largest possible anchoring force against the fallopian tube. Minimizing inner diameter 22 also ensures that anchoring force is applied within the fallopian tube, despite the curvature of the fallopian tube.

30 Referring now to Fig. 2, an alternative embodiment of the present contraceptive intrafallopian device 30 includes additional loops to ensure anchoring of the device within the fallopian tube. Alternative embodiment 30 is formed from an elongate primary coil 32 having a proximal end 34 and a distal
35 end (not shown). Elongate primary coil 32 has an outer diameter 36 which is smaller than the isthmus of the fallopian tube, allowing the straightened intrafallopian device to be inserted easily. Elongate primary coil 32 has been bent to

form a secondary shape including a larger number of loops 38 than the embodiment of Fig. 1. Loops 38 have an outer diameter 40 which is larger than the inner diameter of the fallopian tube, preventing loops 38 from assuming their relaxed shape. Loops 38 are again separated by straight sections 42 of elongate primary coil 32, increasing the overall intrafallopian device diameter 44.

In both embodiments of the present intrafallopian device 10, 30, at least one loop adjacent to the proximal end is disposed proximally of the narrowest portion of the fallopian tube, referred to as the isthmus. Similarly, at least one loop of the intrafallopian device is disposed distally of the isthmus. These proximal and distal loops act as anchors, helping to prevent proximal or distal movement of the intrafallopian device. In the embodiment of Fig. 2, at least one loop is also disposed adjacent to the isthmus of the fallopian tube, further helping to prevent unintentional expulsion.

Alternative intrafallopian device 30 may be positioned with multiple loops acting as proximal or distal anchors, or may alternatively have all but the proximal and distal anchor loops disposed along the fallopian tube to act as anchors within the lumen of that body. Advantageously, the embodiment of Fig. 2 is therefore less sensitive to variations in total fallopian tube length.

Referring now to Fig. 3, a delivery catheter for the present intrafallopian device comprises an elongate body 52 and a shaft 54. Elongate body 52 includes a lumen 56 in which shaft 54 is disposed, shaft 54 being slidable in the axial direction. Shaft 54 includes a core 58 having a tapered distal end 60, allowing the device to navigate through tortuous bends while retaining the column strength required to advance the device. Core 58 extends proximally through elongate body 52, and is capable of transferring compressive forces through the elongate body. Core 58 is typically formed from stainless steel, a stainless alloy, or the like. Disposed over distal end 60 of core 58 is pusher cap 62. Pusher cap 62 provides a low friction, deformable end piece

having a distal coil interface surface 64. Pusher cap 62 is preferably formed of a low friction polymer such as PTFE, or the like.

5 Intrafallopian delivery catheter 50 receives the present intrafallopian device within the distal end of lumen 56 of elongate body 52. Lumen 56 has an inner diameter which is slightly larger than outer diameter 36 of the primary coil. The present intrafallopian device is therefore
10 straightened to a straight configuration as it is loaded proximally into the distal end of lumen 56. Elongate body 52 is sufficiently strong to restrain the primary coil in the straight configuration, but must remain sufficiently flexible to allow maneuvering within the body lumen. Elongate body 52 is preferably formed from an inelastic, flexible material such
15 as polyurethane, PET, or the like.

Referring now to Fig. 4, intrafallopian device 10 is released from delivery catheter 50 within the fallopian tube by holding shaft 54 while proximally withdrawing elongate body 52. Distal coil interface surface 64 engages the proximal end
20 14 of primary coil 12. Initially, primary coil 12 is restrained in a straight configuration by elongate body 52. As elongate body 52 is withdrawn, primary coil 12 is released. When primary coil 12 is unrestrained it forms loop 20; when released within the fallopian tube it will generally be
25 restrained by the tubal wall in a configuration between straight and the relaxed secondary shape. Preferably, the first loop released will form a distal anchor bend 66. Subsequent loops will bias primary coil 12 against the fallopian tube, and form a proximal anchor bend, in that
30 order.

Use of the present contraceptive intrafallopian device will be described with reference to Figs. 5 and 6. A uterine introducer canula 70 is inserted transcervically through a uterus 72 to the region of an ostium 74. Elongate
35 body 52 is then extended distally from canula 70 into a fallopian tube 77, preferably guided under fluoroscopy. Alternatively, a hysteroscope may be used in place of

canula 70. Elongate body 52 is maneuvered using a guide wire 78 past an isthmus 80.

After elongate body 52 extends past isthmus 80, guide wire 78 is removed. An intrafallopian device according to the present invention is inserted in the proximal end of elongate body 52, the intrafallopian device being restrained in a straight configuration by the elongate body. The device is advanced distally using shaft 54, the shaft and elongate body forming delivery catheter 50 (Fig. 3). Delivery catheter 50 is axially positioned so that at least one loop of the intrafallopian device is within a target region 84 adjacent to isthmus 80. Preferably, at least one loop is distal of target region 84, and at least one loop is proximal of target region 84 to form the distal and proximal anchor bends of the implanted intrafallopian device.

Once delivery catheter 50 is properly positioned, elongate body 52 may be axially withdrawn. Shaft 54 axially restrains the intrafallopian device at the target location during withdrawal of elongate body 52, as described regarding Fig. 4. As the distal end of the primary coil is released, the distal loop forms a distal anchor bend 90. Similarly, the proximal loop forms a proximal anchor bend 92. Intermediate loops are restrained within the narrow target region 84, exerting substantial anchoring forces against the walls of the fallopian tube. As seen in Fig. 6, the loops need not assume their relaxed form to provide effective distal or proximal anchors.

The present invention further encompasses permanent sterilization by passing a current through the shaft to the intrafallopian device after elongate body 52 has been partially withdrawn, but before the intrafallopian device is fully released. Fallopian tube tissue in contact with the intrafallopian device is dessechated, and thus attached to the present intrafallopian device. This action also causes permanent tubal damage, leading to the formation of scar tissue which encapsulates the intrafallopian device and causes permanent occlusion of the tubal lumen. Clearly, the

resilient member/shaft interface must be conductive to allow the present non-surgical method of permanent sterilization.

5 In conclusion, the present invention provides a contraceptive intrafallopian device which may be positioned without surgery. While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, a wide variety of secondary shapes, including open loops, continuous bends, sinusoidal curves, or the like, may
10 be imposed on the primary coil. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined instead solely by the appended claims.

WHAT IS CLAIMED IS:

1 1. An intrafallopian contraceptive device
2 comprising:
3 a resilient structure having a proximal end and a
4 distal end, the resilient structure comprising copper and
5 being biased to form at least one proximal anchor adjacent the
6 proximal end and at least one distal anchor adjacent the
7 distal end, the at least one proximal anchor and at least one
8 distal anchor defining an isthmus-traversing region
9 therebetween.

1 2. An intrafallopian contraceptive device as
2 claimed in claim 1, wherein the resilient structure comprises
3 a primary coil.

1 3. An intrafallopian contraceptive device as
2 claimed in claim 2, wherein the primary coil comprises a
3 material selected from the group consisting of beryllium,
4 zinc, stainless steel, platinum, and shape memory alloy.

1 4. An intrafallopian contraceptive device as
2 claimed in claim 3, wherein the primary coil comprises an
3 alloy including beryllium and copper.

1 5. An intrafallopian contraceptive device as
2 claimed in claim 2, wherein the primary coil comprises an
3 alloy including at least 75% copper.

1 6. An intrafallopian contraceptive device as
2 claimed in claim 3, wherein the primary coil comprises a
3 plated layer of a material selected from the group containing
4 copper and copper alloy.

1 7. An intrafallopian contraceptive device as
2 claimed in claim 1, wherein the isthmus-traversing region
3 includes one of the plurality of bends.

1 8. An intrafallopian contraceptive device as
2 claimed in claim 1, further comprising fibers carried on the
3 resilient structure, the fibers comprising a material selected
4 from the group containing copper and polyester.

1 9. An intrafallopian contraceptive device as
2 claimed in claim 1, wherein the resilient structure is
3 restrainable in a straight configuration.

1 10. An intrafallopian contraceptive device as
2 claimed in claim 9, wherein the resilient structure has an
3 outer diameter in the range between .2 mm and 5 mm and a
4 length in the range between 20 mm and 150 mm when in the
5 straight configuration.

1 11. An intrafallopian contraceptive device as
2 claimed in claim 9, wherein the resilient structure has a
3 width of at least 3 mm when in a relaxed state.

1 12. An intrafallopian contraceptive device as
2 claimed in claim 1, wherein the device comprises at least
3 three bends which form loops in the resilient structure when
4 in a relaxed state.

1 13. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the loops are separated by
3 straight sections when in a relaxed state.

1 14. An intrafallopian contraceptive device
2 comprising:
3 a resilient primary coil having a proximal end, a
4 distal end, and a primary coil diameter, wherein:
5 1) the primary coil comprises copper; and
6 2) the primary coil forms a secondary shape
7 when in a relaxed state, the secondary shape defining a
8 plurality of bends and an overall width which is larger
9 than the primary coil diameter.

1 15. An intrafallopian contraceptive device as
2 claimed in claim 14, wherein the primary coil comprises a
3 material selected from the group consisting of beryllium,
4 zinc, stainless steel, platinum, and shape memory alloy.

1 16. An intrafallopian contraceptive device as
2 claimed in claim 14, wherein the coil comprises an alloy
3 including beryllium and copper.

1 17. An intrafallopian contraceptive device as
2 claimed in claim 14, further comprising fibers disposed on the
3 resilient structure, the fibers comprising a material selected
4 from the group containing copper and polyester.

1 18. An intrafallopian contraceptive device as
2 claimed in claim 14, wherein the coil diameter is in the range
3 between .2 mm and 5 mm.

1 19. An intrafallopian contraceptive device as
2 claimed in claim 14, wherein the primary coil has a length in
3 the range between 20 mm and 150 mm when in a straight
4 configuration.

1 20. An intrafallopian contraceptive device as
2 claimed in claim 14, wherein the overall width is at least
3 6 mm.

1 21. An intrafallopian contraceptive device as
2 claimed in claim 14, wherein each of the bends forms a loop in
3 the primary coil.

1 22. An intrafallopian contraceptive device as
2 claimed in claim 21, wherein the loops are separated by
3 straight sections.

1 24. An intrafallopian contraceptive delivery system
2 comprising:

3 an elongate body having a proximal end, a distal
4 end, and a delivery lumen;

5 a resilient primary coil slidably disposed within
6 the elongate body, the primary coil having a proximal end and
7 a distal end, the primary coil comprising copper and being
8 biased to form at least one proximal anchor bend at the
9 proximal end and at least one distal anchor bend at the distal
10 end, the proximal and distal anchor bends defining an isthmus-
11 traversing region therebetween;

12 a shaft slidably disposed within the delivery lumen
13 of the elongate body proximally of the primary coil, the shaft
14 having a coil interface surface near the distal end;

15 wherein the elongate body radially restrains the
16 primary coil in a straight configuration, and the coil may be
17 released by axially restraining the coil against the coil
18 interface surface while proximally withdrawing the elongate
19 body.

1 25. An intrafallopian contraceptive delivery system
2 as claimed in claim 24, wherein the shaft, the coil interface
3 surface, and the coil are electrically conductive.

1 26. An intrafallopian contraceptive method
2 comprising:

3 restraining a resilient structure in a straight
4 configuration, the resilient structure comprising copper and
5 having an isthmus-traversing region which includes at least
6 one bend;

7 transcervically inserting the restrained resilient
8 structure into an isthmus of a fallopian tube;

9 releasing the resilient structure within the
10 isthmus, so that the isthmus-traversing region exerts an
11 anchoring force against a wall of the fallopian tube.

1 27. A method as claimed in claim 26, further
2 comprising:

3 releasing a distal portion of the resilient
4 structure distally of the target region, the distal portion
5 including at least one bend; and

6 releasing a proximal portion of the resilient
7 structure proximally of the target region, the proximal
8 portion including at least one bend.

1 28. A method as claimed in claim 26, wherein the
2 restraining step comprises inserting the resilient structure
3 within a lumen of a catheter, the resilient structure being
4 released within the fallopian tube by axially restraining the
5 resilient structure and proximally withdrawing the catheter.

1 29. A method as claimed in claim 26, further
2 comprising inhibiting fertilization by exposing a multiplicity
3 of copper fibers within the fallopian tube, the fibers being
4 disposed on the resilient structure.

1 30. A method as claimed in claim 26, wherein the
2 introducing step comprises:
3 positioning a distal end of a tubular body adjacent
4 to an ostium;

5 inserting a delivery catheter containing the
6 resilient structure through the tubular body to the target
7 region, the delivery catheter restraining the resilient body
8 in the straight configuration.

1 31. A method as claimed in claim 26, further
2 comprising applying an electrical current through the
3 resilient body to the fallopian tube to effect permanent
4 sterilization.

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND THEIR DELIVERY

ABSTRACT OF THE DISCLOSURE

5 The invention provides intrafallopian devices and
non-surgical methods for their placement to prevent
conception. The efficacy of the device is enhanced by forming
the structure at least in part from copper or a copper alloy.
The device is anchored within the fallopian tube by imposing a
10 secondary shape on a resilient structure, the secondary shape
having a larger cross-section than the fallopian tube. The
resilient structure is restrained in a straight configuration
and transcervically inserted within the fallopian tube, where
it is released. The resilient structure is then restrained by
15 the walls of the fallopian tube, imposing anchoring forces as
it tries to resume the secondary shape.

FIG-2

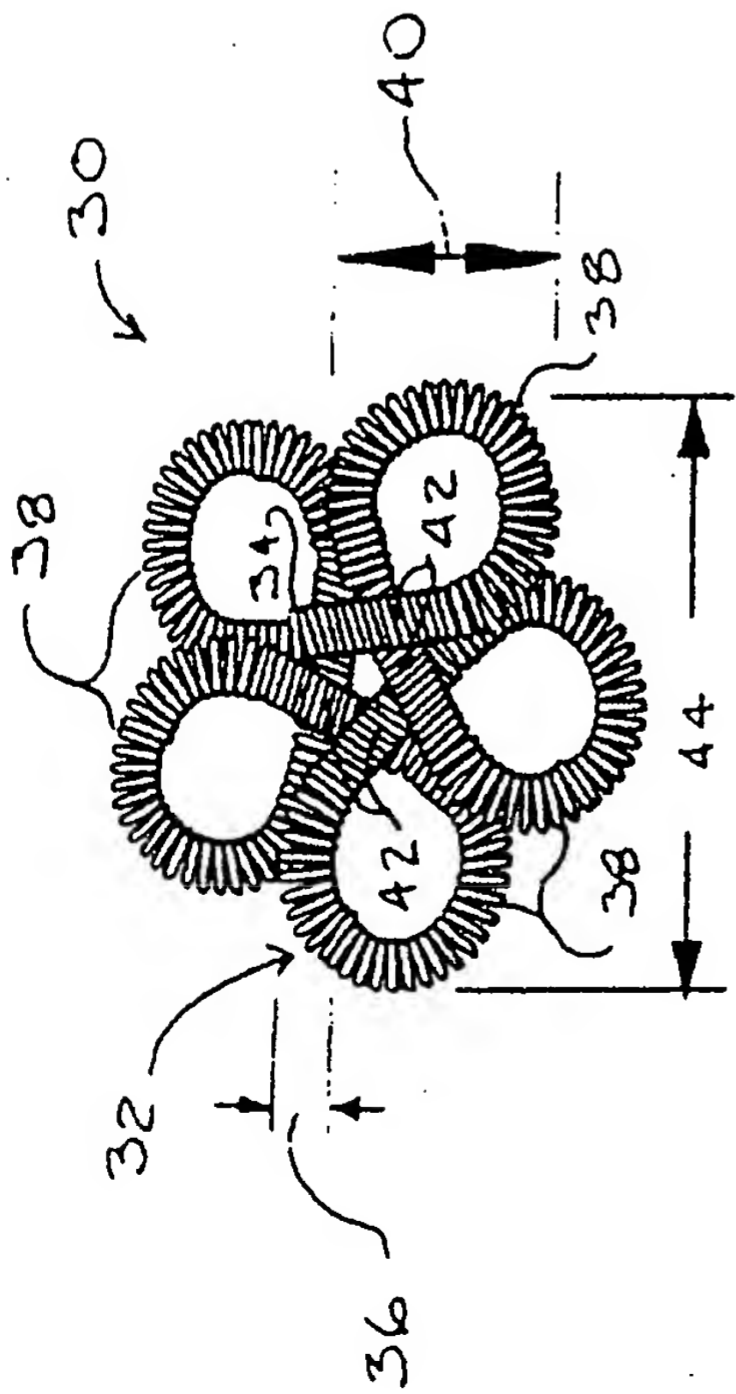


FIG-1

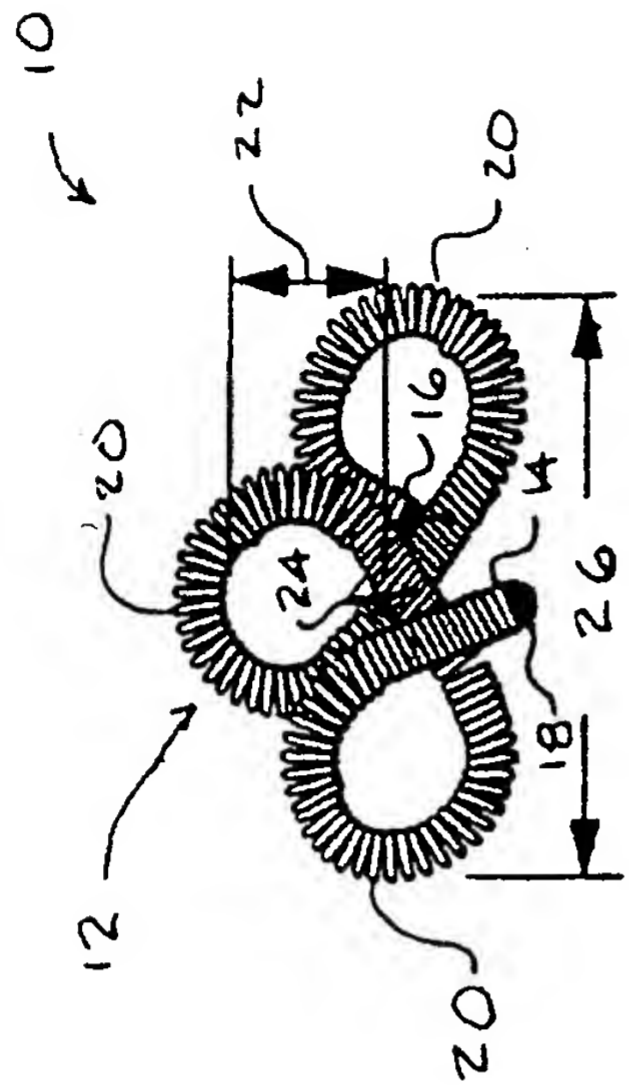
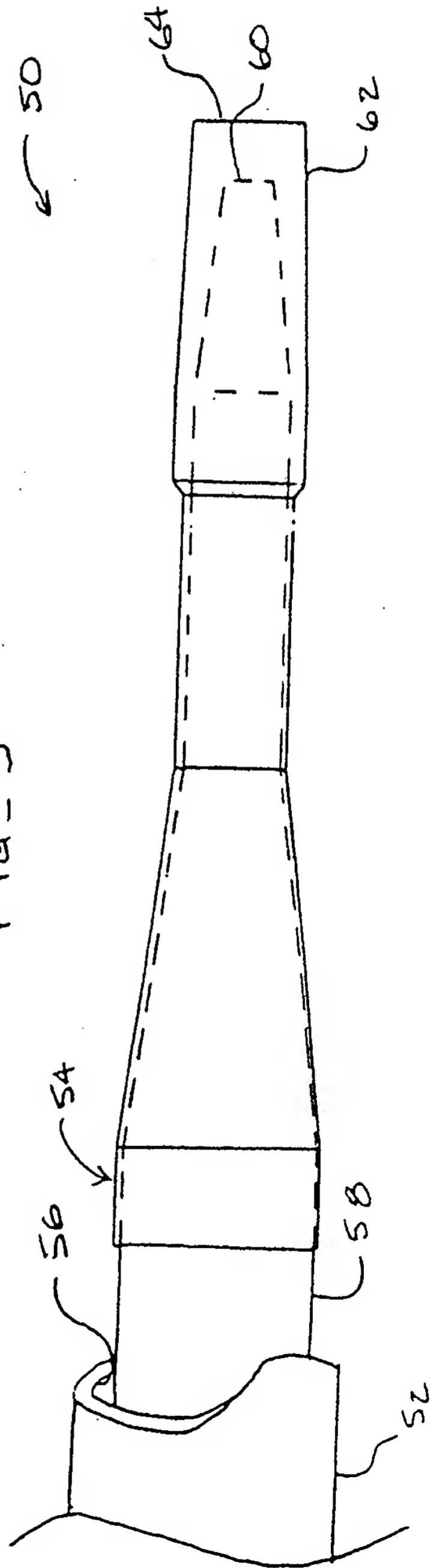
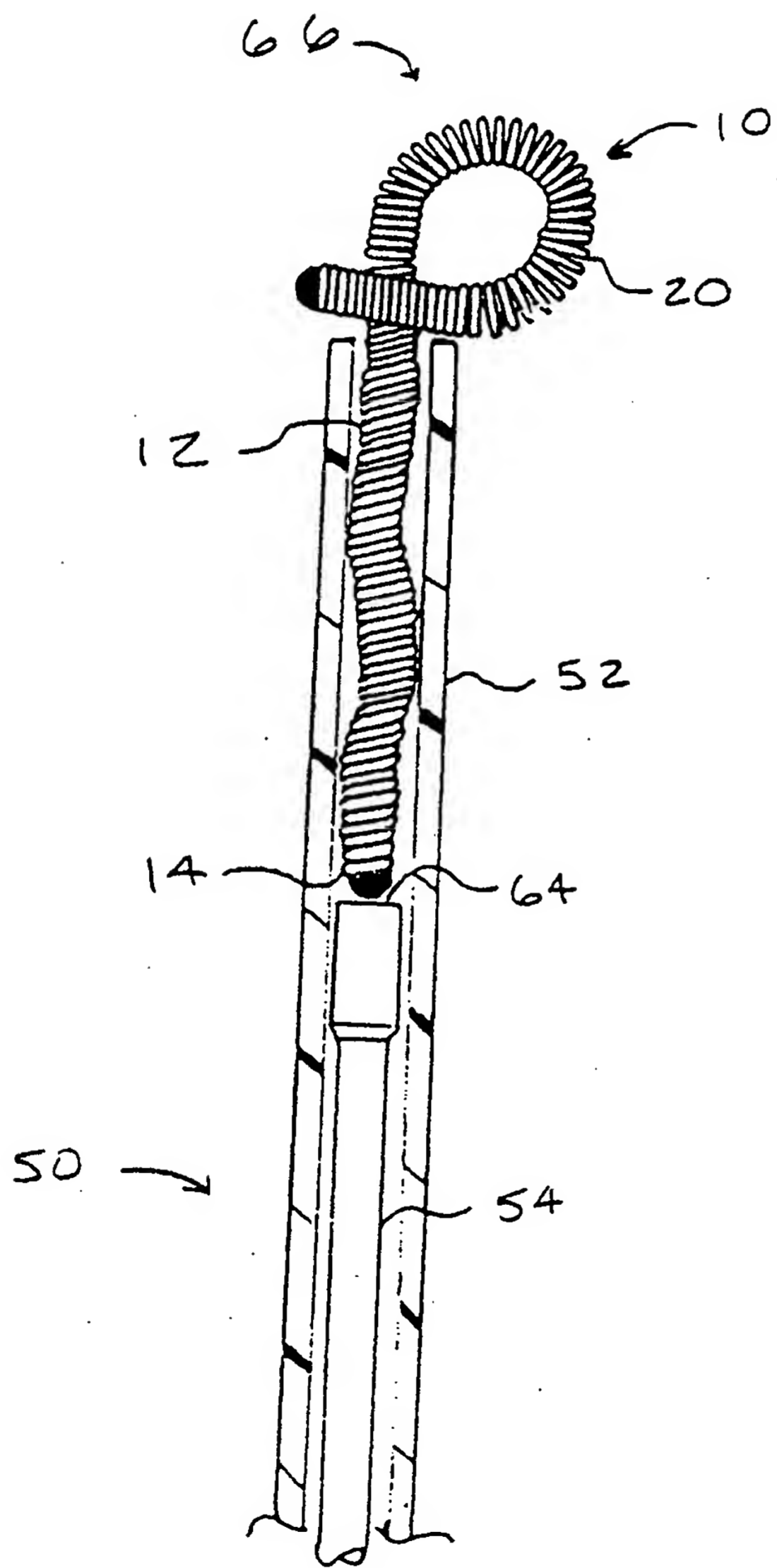


FIG-3





FIG_4

77

FIG- 5

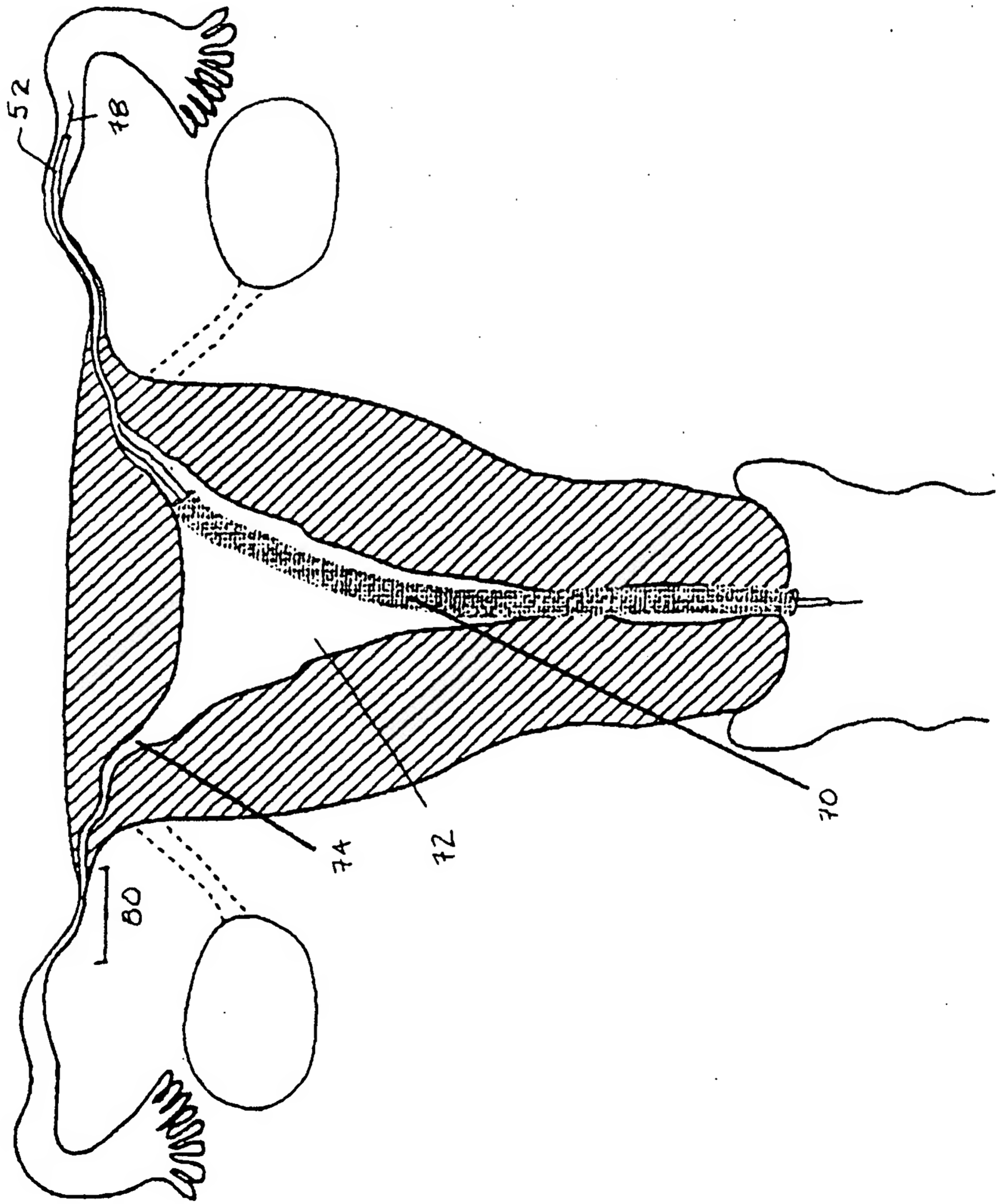
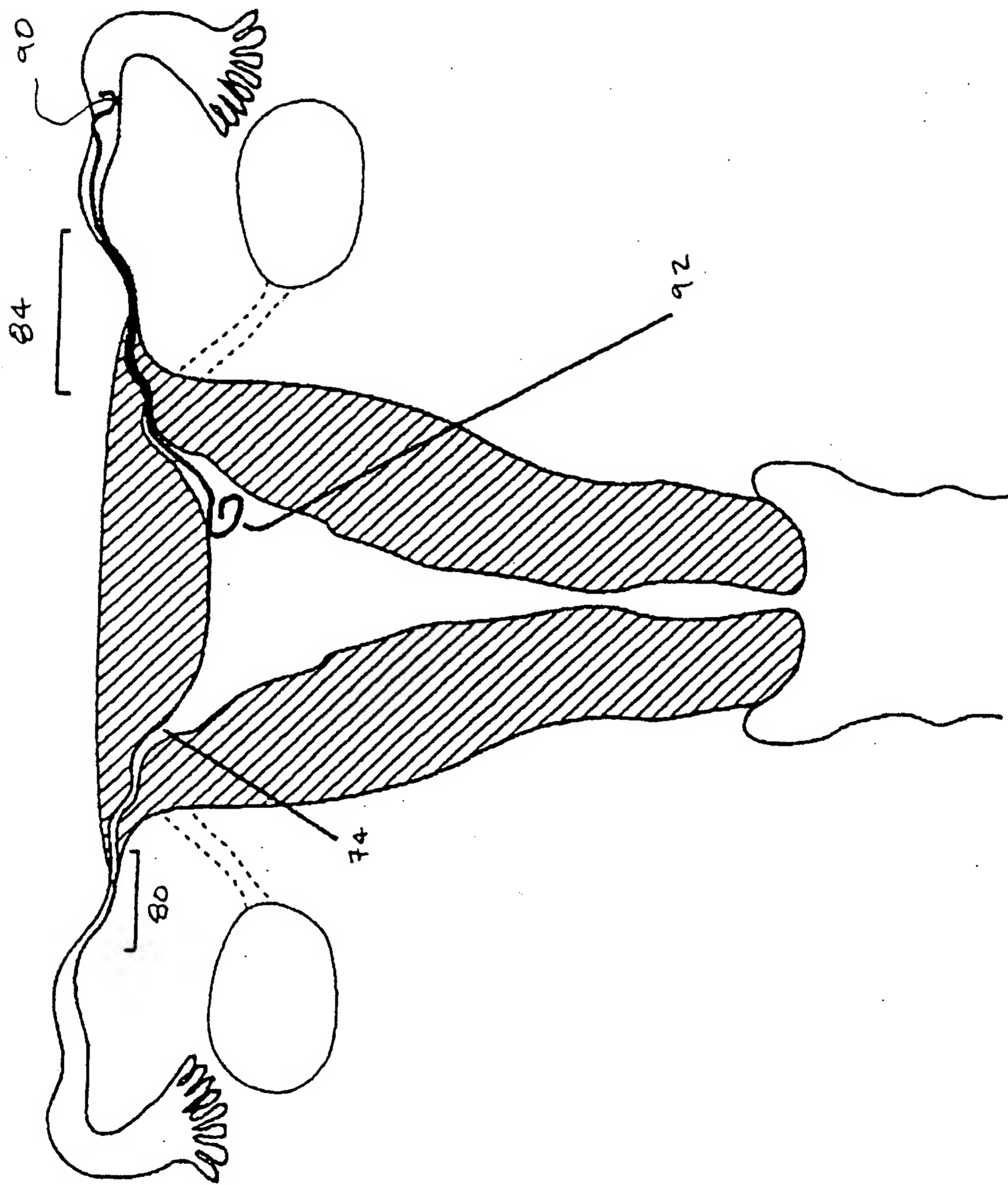


FIG-6




CON '252 App
(1995)

PATENT APPLICATION SERIAL NO. 08/475252

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

260 YC 20-1430 07/03/95 08475252
26057 201 606.00CH 16355-002500

BAR CODE LABEL		U.S. PATENT APPLICATION			
					
SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT		
08/475,252	06/07/95	128	3301		
APPLICANT	JULIAN NIKOLCHEV, PORTOLA VALLEY, CA; DAI TON, SAN JOSE, CA.				
	CONTINUING DATA*** VERIFIED _____				
	FOREIGN/PCT APPLICATIONS*** VERIFIED _____				
FOREIGN FILING LICENSE GRANTED 08/01/95 ***** SMALL ENTITY *****					
STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.
CA	5	35	5	\$606.00	16355-002500
ADDRESS	TOWNSEND AND TOWNSEND KHOURIE AND CREW STEUART STREET TOWER ONE MARKET PLAZA SAN FRANCISCO CA 94105				
TITLE	CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT				
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PATENT APPLICATION
COMMISSIONER OF PATENT AND TRADEMARKS
Washington, D. C. 20231

Sir:

Transmitted herewith for filing is the ☒ patent application,
☐ continuation-in-part patent application of

Inventors: JULIAN NIKOLCHEV and DAI TON

For: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION
DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT

Enclosed are:

- ☒ Five sheet(s) of ☐ formal ☒ informal drawing(s).
☒ An assignment of the invention to Conceptus, Inc., a California corporation.
☐ A ☐ signed ☐ unsigned Declaration & Power of Attorney.
☒ A ☒ signed ☐ unsigned Declaration.
☒ A Power of Attorney by Assignee with Certificate Under 37 C.F.R. Section 3.73(b).
☒ A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27.
☐ A certified copy of a _____ application.
☐ Information Disclosure Statement under 37 CFR 1.97.
☐ Enclosed is a petition to extend time to respond in the parent application of the continuation-in-part application.
☐

The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)
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TOTAL CLAIMS	35 -20=	* 15
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Atty. Docket No. 08/475252
355-002500
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By Donald J. Barrish

SMALL ENTITY		OR	OTHER THAN A SMALL ENTITY	
RATE	FEE		RATE	FEE
	\$ 365	OR		\$730
15 x11=	\$ 165	OR	x22=	\$
2 x38=	\$ 76	OR	x76=	\$
+120=	\$ --	OR	+240=	\$
TOTAL	\$ 606	OR	TOTAL	\$

Respectfully submitted,
TOWNSEND and TOWNSEND KHOURIE and CREW

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Reg. No. 36,443
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Attorney Docket No. 16355-25
Client Reference No. 95003-1

PATENT APPLICATION



CONTRACEPTIVE transcervical fallopian
tube occlusion devices having mechanical fallopian
tube attachment

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08/475252 A

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PATENT

Attorney Docket No. 16355-25



CONTRACEPTIVE TRANSCERVICAL FALLOPIAN
TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN
TUBE ATTACHMENT

BACKGROUND OF THE INVENTION

1. Field of the Invention

10 The present invention relates generally to
contraception, and more particularly to intrafallopian
contraceptive devices and nonsurgical methods for their
delivery.

15 Worldwide demand exists for safe, effective methods
of both contraception and permanent sterilization. Although a
variety of contraception and sterilization methods are
available, all of the existing methods have limitations and
disadvantages. Thus, the need for additional safe, low cost,
20 reliable methods of contraception and permanent sterilization,
both in developed and less developed countries, is widely
recognized.

25 Many presently available contraception methods
require significant user involvement, and user non-compliance
results in quite high rates of failure. While the theoretical
effectiveness of existing contraceptives, including barrier
methods and hormonal therapies, is well established,
overcoming user noncompliance to improve overall efficacy has
proven difficult.

30 One form of contraception which is less susceptible
to user noncompliance is the intrauterine device (IUD). IUDs
have been found to have higher rates of reliability, and are
effective for a longer period of time, than most other
commercially available contraceptives. Unfortunately, IUDs
are also associated with serious infectious complications.
35 For this reason, the use of IUDs within the United States has
decreased dramatically. Additionally, IUDs are subject to
unplanned expulsion, and must be removed due to excessive pain
or bleeding in a percentage of cases, further reducing the

acceptance of the IUD as a contraceptive method. Interestingly, the efficacy of copper IUDs appears to be higher than that of non-metallic IUDs. The reason for this has not been fully explained.

5 Commercially available options for permanent sterilization include fallopian tube ligation and vasectomy. These methods are surgical, are difficult to reverse, and are not available to many people in the world. It is common knowledge that fertilization occurs in the fallopian tubes
10 where the sperm and ovum meet. Tubal ligation avoids this by complete occlusion of the fallopian tubes.

 It has previously been proposed to reversibly occlude the fallopian tubes, for example, by *in vitro* formation of an elastomeric plug, or otherwise anchoring a
15 device on either side of the narrowest region of fallopian tube, called the "isthmus." Such fallopian tube occlusion methods appear promising; however, an unacceptably high percentage of the non-surgical devices proposed to date have become dislodged during previous studies. Even where non-
20 surgical intrafallopian devices have remained in place, they have been found to be only moderately effective at preventing conception.

 For these reasons, it would be desirable to provide effective, reliable intrafallopian devices for contraception
25 and sterilization. It would be particularly desirable to provide highly effective intrafallopian devices which did not require surgery for placement. It would be especially desirable if such devices and methods allowed easy placement of the device, but were less susceptible to being dislodged
30 than previously proposed non-surgical intrafallopian devices.

2. Description of the Related Art

 The experimental use of a stainless steel intrafallopian device is described in *Transcatheter Tubal Sterilization in Rabbits*, Penny L. Ross, RT 29 "Investigative
35 Radiology", pp. 570-573 (1994). The experimental use of an electrolytically pure copper wire as a surgical contraceptive intrafallopian device in rats was described in "Antifertility

Effect of an Intrafallopian Tubal Copper Device", D.N. Gupta, 14 *Indian Journal of Experimental Biology*, pp. 316-319 (May 1976).

U.K. Patent Application Pub. No. 2,211,095 describes a uterine screw plug for blocking the fallopian tube. European Patent Application Pub. No. 0,010,812 describes a device for placement in the oviducts having enlargements at either end for anchoring the device. The same device appears to be described in Netherlands Patent No. 7,810,696.

The use of tubal occlusion devices is described in "Hysteroscopic Oviduct Blocking With Formed-in-Place Silicone Rubber Plugs", Robert A. Erb, Ph.D., et al., *The Journal of Reproductive Medicine*, pp. 65-68 (August 1979). A formed-in-place elastomeric tubal occlusion device is described in U.S. Patent No. 3,805,767, issued to Erb. U.S. Patent No. 5,065,751, issued to Wolf, describes a method and apparatus for reversibly occluding a biological tube. U.S. Patent No. 4,612,924, issued to Cimber, describes an intrauterine contraceptive device which seals the mouths of the fallopian tubes.

German Patent No. 28 03 685, issued to Brundin, describes a device for plugging a body duct with a device which swells when in contact with a body fluid.

Alternative contraceptive devices are disclosed in copending U.S. Patent Application Serial No. 08/474,779 (~~attorney docket no. 16355-24~~), the full disclosure of which is herein incorporated by reference.

SUMMARY OF THE INVENTION

The present invention provides intrafallopian devices and methods for their placement to prevent conception. The intrafallopian devices of the present invention are transcevically delivered and mechanically anchored within the fallopian tube to provide long term contraception, or alternatively permanent sterilization, without the need for surgical procedures or the risks of increased bleeding, pain, and infection associated with intrauterine devices (IUDs).

The intrafallopian devices of the present invention generally comprise a structure having a lumen-traversing region with a helical outer surface. The helical surface is mechanically anchored by a resilient portion of the structure which is biased to form an enlarged secondary shape, preferably forming distal and proximal anchoring loops. The anchoring loops help prevent the helical outer surface from rotating out of position, and also directly deter axial motion within the fallopian tube.

The use of copper in the intrafallopian device of the present invention improves its efficacy as a contraceptive method. Devices formed from plastically deformable materials, however, are less readily restrained in the fallopian tube. Apparently, the large variation in the actual shape and dimensions of fallopian tubes does not provide reliable anchoring for a pre-formed deformable intrafallopian device. The intrafallopian device of the present invention therefore comprises a resilient structure, usually a metallic coil, which includes a copper alloy or plating, ideally comprising an alloy including at least 75% copper. The coil material typically includes beryllium, zinc, stainless steel, platinum, a shape memory alloy, such as Nitinol[™], or the like. Preferably, the coil is composed of an alloy of beryllium and copper. Although the present device will generally result in occlusion, it need not completely occlude the fallopian tube to prevent the meeting of the sperm and ovum. Instead, the presence of the copper on the resilient structure is sufficient to provide effective contraception.

Conveniently, the present invention further comprises non-surgical placement of such intrafallopian devices by transcervical introduction. The resilient structure is restrainable in a straight configuration, e.g., by use of a corewire, greatly facilitating and reducing the risks of introduction. Thus, the cost and dangers associated with existing surgical contraceptive and sterilization procedures are avoided.

In a first aspect, a contraceptive intrafallopian device according to the present invention comprises a proximal anchor, a distal anchor, and a lumen-traversing region extending between the anchors. The lumen traversing region has a helical outer surface and a cross-section which is smaller than the cross-sections of the proximal and distal anchors.

Preferably, the lumen-traversing region comprises a resilient structure, generally having a ribbon wound over the outer surface to form the helical shape. Anchoring is enhanced by a sharp outer edge on the ribbon. As described above, at least one of the proximal anchor, the distal anchor, and the lumen-traversing region preferably comprises copper. The proximal and distal anchors generally comprise a resilient structure biased to form an enlarged secondary shape, thereby allowing the device to be restrained in a straight configuration to facilitate transcervical introduction.

In another aspect, a contraceptive intrafallopian device according to the present invention comprises a primary coil having a proximal loop, a distal loop, and an intermediate straight section between the loops. A helical ribbon is wound over at least a portion of the intermediate section, forming a helical surface to mechanically anchor the device within the fallopian tube.

The ribbon of the present intrafallopian device generally protrudes sufficiently to firmly engage the tubal wall. Preferably, the ribbon has a width in the range between .005 and .1 inch, a thickness in the range between .001 and .2 inch, and a pitch in the range between .01 and .2 inch. The overall device geometry preferably facilitates introduction and retention, but is not large or rigid enough to interfere with internal tissue movements. Usually, the device has a length in the range between 1.5 cm and 7.5 cm when in a relaxed state, while the distal loop and the proximal loop have outer diameters of at least 3 mm. Preferably, the primary coil has an outer diameter in the range between .2 mm and 5 mm.

In another aspect, a system for delivering intrafallopian contraceptive devices according to the present invention comprises a primary coil having a proximal loop, a distal loop, and an intermediate straight section between the loops. Additionally, a lumen extends from a proximal end of the proximal loop to near a distal end of the distal loop. A helical ribbon is wound over at least a portion of the intermediate section, forming a helical surface to mechanically anchor the device within the fallopian tube. A corewire is removably disposed within the lumen of the primary coil. The corewire restrains the primary coil in a straight configuration, facilitating transcervical introduction. Optionally, the corewire is threadably received by the primary coil. Alternatively, a release catheter is slidably disposed over the corewire proximally of the primary coil to restrain the primary coil while the corewire is withdrawn proximally from the fallopian tube.

The helical ribbon is anchored in the fallopian tube by the distal and proximal loops. The ribbon is set in the tubal wall while the device is restrained in a straight configuration over a corewire by torquing on the corewire. Withdrawing of the corewire then releases the anchors. The distal anchor is generally inserted into the ampulla, distal of the isthmus, while the proximal anchor is located in the ostium. These anchors prevent rotation of the device, and also help avoid axial movement.

In yet another aspect, an intrafallopian contraceptive method according to the principles of the present invention comprises restraining a resilient contraceptive structure in a straight configuration over a corewire, where the resilient structure includes a lumen-traversing region having a helical outer surface. The resilient structure is transcervically introduced into a target region of a fallopian tube, typically in the region of the ostium, and the corewire is withdrawn from the resilient structure. The resilient structure is mechanically anchored within the fallopian tube, a portion of the resilient structure assuming an enlarged secondary shape which is larger

in cross-section than the fallopian tube. Optionally, an electric current is applied through the resilient structure to the fallopian tube, thereby effecting permanent sterilization.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a first embodiment of a contraceptive intrafallopian device according to the present invention.

10 Fig. 2 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 1.

Fig. 3 illustrates a secondary coil which has been imposed on a primary coil as used in the contraceptive intrafallopian device of Fig. 1.

15 Fig. 4 illustrates a corewire for use with the contraceptive intrafallopian device of Fig. 1.

Fig. 5 is a cross-sectional view of a contraceptive delivery system having the contraceptive intrafallopian device of Fig. 1.

20 Fig. 6 illustrates an alternative embodiment of the present contraceptive intrafallopian device.

Fig. 7 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 6.

25 Fig. 8 schematically illustrates a contraceptive delivery system including the contraceptive intrafallopian device of Fig. 6.

Figs. 9 and 10 illustrates a method of delivery of a contraceptive intrafallopian device according to the present invention.

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DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENT

The present invention encompasses a contraceptive intrafallopian device which can alternatively be used as both a permanent and a reversible means of contraception. The present contraceptive methods and devices minimize the danger
35 of non-use which has limited the efficacy of prior art contraceptive techniques. Moreover, the location of the present devices within the fallopian tubes provides a reduced risk of the infectious complications, increased bleeding, and

pelvic pain associated with intrauterine devices (IUDs). The location and the novel shape of the present intrafallopian device provides significant advantages over IUDs, which have been found to be susceptible to unplanned expulsion and removal due to excessive pain and bleeding. The present invention takes advantage of the increase in effectiveness associated with copper IUDs, providing a resilient structure including copper which may be transcervically positioned without the need for surgery.

Although the present contraceptive method is included within a group of contraceptive techniques generally referred to as fallopian tube occlusion methods, the present invention does not necessarily rely solely on blocking the fallopian tube to prevent fertilization. Instead, contraception is apparently provided by disrupting of ovum transport, the process of fertilization, and/or cleavage of the ovum. While the effect that copper has on these processes is not fully understood, it does appear that copper intrafallopian devices offer potentially significant increases in effectiveness over intrafallopian devices formed of other materials. Optionally, the present invention further encompasses devices which promote the growth of tissue within the tube to induce tubal occlusion, further inhibiting conception.

Conveniently, the present resilient structures are adapted to be releasably affixed over a corewire, the corewire restraining the resilient structure in a straight configuration. As the resilient structure has an outer diameter when in the straight configuration which is less than the inner diameter of the fallopian tube, the catheter containing the present intrafallopian device is easily transcervically introduced.

The present invention is anchored within the isthmus of the fallopian tube, overcoming the unintended expulsion of the device and the resulting failure of the contraceptive method. Such intrafallopian device expulsion has been the single greatest factor limiting the efficacy of easily positioned intrafallopian contraceptive techniques. The

present intrafallopian devices are generally elongate resilient structures pre-formed into secondary shapes. These secondary shapes will preferably form anchors proximally and distally of the narrowest portion of the fallopian tube, called the isthmus. The secondary shape must have a larger outer diameter than the inner diameter of the isthmus.

The present device is generally readily removed by snaring the resilient structure near the proximal end and pulling proximally on the resilient structure, thereby straightening the resilient structure and allowing it to be withdrawn without injuring the fallopian tube. Alternatively, an electrical current is applied to the device after it is positioned within the fallopian tube, providing permanent sterilization.

Referring now to Fig. 1, a first embodiment of the present contraceptive intrafallopian device 10 is formed from a resilient primary coil 12. Primary coil 12 has a proximal end 14 and a distal end 16, the latter having an atraumatic endcap 18. Primary coil 12 further includes three portions: a proximal anchor portion 20, a distal anchor portion 22, and a lumen-traversing region 24. Proximal and distal anchors 20, 22 are biased to form anchoring loops 26, as described hereinbelow.

Lumen-traversing region 24 comprises a substantially straight portion of primary coil 12. A ribbon 28 is wound over the outer surface of primary coil 12 to provide a helical shape. Ribbon 28 includes sharp outer edges 29, which firmly anchor lumen-traversing region 24 in the fallopian tube wall when torque is applied to intrafallopian device 10. The ribbon is preferably formed of a high strength biocompatible metal, ideally being stainless steel. The ribbon is attached to primary coil 12 at a proximal joint 30 and a distal joint 32, which may be formed of solder, heat-shrink tubing, or the like.

Referring now to Fig. 2, primary coil 12 is most easily formed in a straight configuration as a cylindrical coil or spring, preferably having an outer diameter in the range from .005 inch to .05 inch, and having a length in the

range from 20 mm to 150 mm. Ideally, primary coil 12 has an outer diameter in the range from .01 inch to .05 inch and a length in the range from 30 mm to 125 mm.

Preferably, primary coil 12 is formed from a beryllium copper alloy wire. Beryllium copper provides the resilience necessary to avoid expulsion of the device, and also provides the increased effectiveness of a copper contraceptive intrafallopian device. Such a beryllium copper wire will typically have a diameter from .002 inch to .01 inch. To provide the increased efficacy of a copper intrafallopian device, primary coil 12 preferably comprises an alloy including 75% copper. Alternatively, primary coil 12 is formed from a resilient metal, such as stainless steel, platinum, a shape memory alloy, or the like. If such materials are used, primary coil 12 is preferably plated with copper or a copper alloy or otherwise has copper attached.

Primary coil 12 includes a body winding 42 and a thread winding 44. Body winding 42 is formed with the minimum possible pitch to increase the stiffness of primary coil 12. Thread winding 44 will typically comprise from 0.1 cm to 2 cm adjacent to proximal end 14, and will have a pitch roughly twice that of body winding 42.

Referring now to Fig. 3, the proximal and distal anchors are formed by imposing a bent secondary shape on selected portions of primary coil 12. The secondary shape preferably comprises loops 26 formed by bending primary coil 12, and heat treating the primary coil while it is bent. A wide variety of secondary shapes may be used, including sinusoidal curves, alternating loops, or loops separated by straight sections so as to form a "flower coil," as more fully described in copending U.S. Patent Application Serial No.

08/474,779
 (Attorney Docket No. 16355-24) the full disclosure of which is herein incorporated by reference. In all cases, the bent secondary shape should have an outer cross-section 46 which is larger than the fallopian tube to provide effective anchoring.

Referring now to Fig. 4, a corewire 50 for use with intrafallopian device 10 (Fig. 1) comprises a resilient wire

52 which tapers towards a distal end 54. Wire 52 is sufficiently stiff to restrain intrafallopian device 10 in a straight configuration, typically comprising stainless steel, platinum, or the like. A short section of coil forms corewire threads 56 attached at threadjoint 58. Threads 56 match the windings and pitch of threadwindings 44 of primary coil 12.

Referring now to Fig. 5, an intrafallopian contraceptive system 60 comprises corewire 50 inserted within a lumen 62 through intrafallopian device 10. Intrafallopian device 10 is releasably attached by engaging thread windings 44 with threads 56. Thus, intrafallopian device 10 is disengaged by torquing a proximal end of corewire 50 once intrafallopian device 10 is in position.

Referring now to Fig. 6, an alternative embodiment of the present intrafallopian device is again formed from a resilient primary coil 112 having a proximal end 114 and a distal end 116. The former includes a friction fitting 115. Primary coil 112 again includes three portions: a proximal anchor portion 120, a distal anchor portion 122, and a lumen-traversing region 124. Proximal and distal anchors 120, 122 are here biased to form opposed anchoring loops 26, thereby increasing the relaxed overall cross-section of the proximal and distal anchors. A ribbon 128 is wound over the outer surface of primary coil 112 to provide a helical shape, as described above.

Referring now to Fig. 7, primary coil 112 comprises a uniform body winding 142. The secondary shape is imposed on the straight cylindrical coil as opposed loops 126, or alternatively as multiple loops of a flower coil.

Referring now to Fig. 8, an intrafallopian contraceptive system using alternative intrafallopian device 100 includes a corewire 152 which tapers towards a distal end 154. Friction fitting 115 fittingly engages corewire 152, which restrains primary coil 112 in a straight configuration. A release catheter 164 is slidably disposed over corewire 152 proximally of alternative intrafallopian device 100, allowing the device to be released by withdrawing corewire 152 relative to the release catheter.

Use of the present contraceptive intrafallopian device will be described with reference to Figs. 9 and 10. A uterine introducer cannula 70 is inserted transcervically through a uterus 72 to the region of an ostium 74.

5 Alternatively, a hysteroscope may be used in place of cannula 70.

Intrafallopian contraceptive system 60 is advanced distally of introducer cannula 70 and maneuvered through the fallopian tube, preferably until intrafallopian device 10
10 extends distally of the isthmus. Optionally, intrafallopian contraceptive system 60 is self-guided, with corewire 52 bent near distal end 54 to assist intraluminal maneuvering. Alternatively, a guide wire and catheter are advanced into the fallopian tube first, and the guide wire is replaced with
15 intrafallopian contraceptive system 60. In either case, the intrafallopian device is axially positioned with lumen-traversing region 24 within a target region 84 adjacent to isthmus 80. Preferably, at least one loop of distal anchor 22 is distal of target region 84, and at least one loop of
20 proximal anchor 20 is proximal of target region 84 to form the distal and proximal anchor bends.

Once intrafallopian device 10 is properly positioned, corewire 50 is torqued to set ribbon 28 in the tubal wall. The corewire may then be unthreaded from
25 intrafallopian device 10 by rotating the corewire in the opposite direction, disengaging threads 56 from thread windings 44. The corewire is then free to slide proximally, releasing the primary coil. As the distal end of the primary coil is released, a distal anchor bend 90 is formed.
30 Similarly, a proximal loop forms a proximal anchor bend 92. The anchor bends help to axially restrain the device within the fallopian tube, and also prevent rotation around the helical shape of lumen-traversing region 24. As seen in Fig. 10, the loops need not assume their relaxed form to
35 provide effective distal or proximal anchors.

The present invention further encompasses permanent sterilization by passing a current through the corewire to the intrafallopian device prior to withdrawing the corewire.

Fallopian tube tissue in contact with the intrafallopian device is dessechated, and thus attached to the present intrafallopian device. This action also causes permanent tubal damage, leading to the formation of scar tissue which encapsulates the intrafallopian device and causes permanent occlusion of the tubal lumen. Clearly, the corewire/primary coil interface must be conductive to allow the present non-surgical method of permanent sterilization.

In conclusion, the present invention provides a contraceptive intrafallopian device which may be positioned without surgery. While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, a wide variety of secondary shapes, including open loops, continuous bends, sinusoidal curves, or the like, may be imposed on the primary coil. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined instead solely by the appended claims.

WHAT IS CLAIMED IS:

1 *Sub a2* 1. An intrafallopian contraceptive device
 2 comprising:
 3 a proximal anchor having a proximal cross-section;
 4 a distal anchor having a distal cross-section; and
 5 a lumen-traversing region extending between the
 6 proximal anchor and the distal anchor, the lumen traversing
 7 region having a helical outer surface and a helical cross-
 8 section which is smaller than both the proximal cross-section
 9 and the distal cross-section.

1 2. An intrafallopian contraceptive device as
 2 claimed in claim 1, wherein the lumen-traversing region
 3 comprises a resilient structure.

1 *Sub a3* 3. An intrafallopian contraceptive device as
 2 claimed in claim 2, wherein the lumen-traversing region
 3 further comprises a ribbon wound over the outer surface of the
 4 resilient structure.

1 4. An intrafallopian contraceptive device as
 2 claimed in claim 2, wherein the ribbon includes a sharp outer
 3 edge.

1 5. An intrafallopian contraceptive device as
 2 claimed in claim 1 wherein at least one of the proximal
 3 anchor, the distal anchor, and the lumen-traversing region
 4 comprises copper.

1 6. An intrafallopian contraceptive device as
 2 claimed in claim 1 wherein at least one of the proximal anchor
 3 and the distal anchor comprises a resilient structure biased
 4 to form a secondary shape.

1 *Sub a4* 7. An intrafallopian contraceptive device as
 2 claimed in claim 6, wherein the resilient structure comprises
 3 a primary coil.

1 8. An intrafallopian contraceptive device as
2 claimed in claim 7, wherein the primary coil comprises a
3 material selected from the group consisting of beryllium,
4 stainless steel, platinum, and shape memory alloy.

1 9. An intrafallopian contraceptive device as
2 claimed in claim 8, wherein the primary coil comprises an
3 alloy including beryllium and copper.

1 10. An intrafallopian device as claimed in claim 7,
2 wherein the primary coil comprises an alloy including at least
3 75% copper.

1 11. An intrafallopian contraceptive device as
2 claimed in claim 1, wherein a lumen extends from a proximal
3 end of the proximal anchor to near a distal end of the distal
4 anchor.

1 12. An intrafallopian contraceptive device
2 comprising:
3 a primary coil having a distal loop, a proximal
4 loop, and an intermediate straight section between the distal
5 loop and the proximal loop; and
6 a helical ribbon wound over at least a portion of
7 the intermediate section.

1 13. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the ribbon has a width in the
3 range between .005 and .1 inch.

1 14. An intrafallopian contraceptive device as
2 claimed in claim 13, wherein the ribbon has a thickness in the
3 range between .001 and .2 inch.

1 15. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the ribbon has a pitch in the
3 range between .01 and .2 inch.

1 16. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the device has a length in the
3 range between 1.5 cm and 7.5 cm when in a relaxed state.

1 17. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the device comprises copper.

1 18. An intrafallopian contraceptive device as
2 claimed in claim 17, wherein the primary coil comprises a
3 material selected from the group consisting of beryllium,
4 stainless steel, platinum, and shape memory alloy.

1 19. An intrafallopian contraceptive device as
2 claimed in claim 18, wherein the primary coil comprises an
3 alloy including beryllium and copper.

1 20. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the primary coil includes a lumen
3 which extends from a proximal end of the proximal loop to near
4 the distal end of the distal loop.

1 21. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the primary coil has an outer
3 diameter in the range between .2 mm and 5 mm.

1 22. An intrafallopian contraceptive device as
2 claimed in claim 12, wherein the distal loop and the proximal
3 loop have outer diameters of at least 3 mm when in a relaxed
4 state.

1 23. An intrafallopian contraceptive system
2 comprising:
3 a primary coil having a distal loop, a proximal
4 loop, an intermediate straight section between the distal loop
5 and the proximal loop, and a lumen from a proximal end of the
6 proximal loop to near a distal end of the distal loop;
7 a helical ribbon wound over at least a portion of
8 the intermediate section; and

9 a corewire removably disposed within the lumen of
10 the primary coil, the corewire restraining the primary coil in
11 a straight configuration.

1 24. An intrafallopian contraceptive system as
2 claimed in claim 23, wherein the primary coil comprises
3 copper.

1 25. An intrafallopian contraceptive system as
2 claimed in claim 23, wherein the corewire is threadably
3 received by the primary coil.

1 26. An intrafallopian contraceptive system as
2 claimed in claim 23, further comprising a release catheter
3 slidably disposed over the corewire proximally of the primary
4 coil, the release catheter having a distal primary coil
5 engaging surface for restraining the primary coil while the
6 corewire is withdrawn proximally.

1 27. An intrafallopian contraceptive method
2 comprising:
3 restraining a resilient structure in a straight
4 configuration over a corewire, the resilient structure
5 including a lumen-traversing region having a helical outer
6 surface;
7 transcervically introducing the resilient structure
8 into a target region of a fallopian tube; and
9 withdrawing the corewire from the resilient
10 structure to mechanically anchor the resilient structure
11 within the fallopian tube, at least a portion of the resilient
12 structure assuming a secondary shape which is larger in cross-
13 section than the fallopian tube.

1 28. A method as claimed in claim 27, wherein the
2 target region is adjacent to an ostium of the fallopian tube.

1 29. A method as claimed in claim 28, wherein the
2 target region extends distally of an isthmus of the fallopian
3 tube.

1 30. A method as claimed in claim 27, further
2 comprising torquing the corewire to anchor the resilient
3 structure, the helical shape having a sharp outer edge.

1 31. A method as claimed in claim 27, wherein the
2 withdrawing step comprises forming a distal anchor from a
3 portion of the resilient structure which is distal of the
4 lumen-traversing region, and forming a proximal anchor from a
5 portion of the resilient structure which is proximal of the
6 lumen-traversing region, the distal portion and the proximal
7 portion assuming the secondary shape.

1 32. A method as claimed in claim 27, wherein the
2 withdrawing step comprises unthreading the corewire from the
3 resilient structure.

1 33. A method as claimed in claim 27, wherein the
2 withdrawing step comprises axially restraining the resilient
3 structure with a release catheter, the release catheter being
4 slidably disposed over the corewire proximally of the
5 resilient structure.

1 34. A method as claimed in claim 27, further
2 comprising applying an electrical current through the
3 resilient structure to the fallopian tube to permanently
4 prevent conception.

- 1 35. An intrafallopian sterilization method
2 comprising:
3 transcervically introducing a structure into a
4 target region of a fallopian tube, the structure being
5 releasably attached to a distal end of an elongate body;
6 applying an electrical current through the elongate
7 body to the structure, and through the structure to the
8 fallopian tube to permanently anchor the structure within the
9 fallopian tube; and
10 releasing the structure from the elongate body and
11 withdrawing the elongate body.

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CONTRACEPTIVE TRANSCERVICAL FALLOPIAN
TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN
TUBE ATTACHMENT



ABSTRACT OF THE DISCLOSURE

The invention provides intrafallopian devices and non-surgical methods for their placement to prevent conception. The efficacy of the device is enhanced by forming the structure at least in part from copper or a copper alloy.

10 The device is anchored within the fallopian tube by a lumen-traversing region of the resilient structure which has a helical outer surface, together with a portion of the resilient structure which is biased to form a bent secondary shape, the secondary shape having a larger cross-section than

15 the fallopian tube. The resilient structure is restrained in a straight configuration and transcervically inserted within the fallopian tube, where it is released. Optionally, permanent sterilization is effected by passing a current through the resilient structure to the tubal walls.

20

DECLARATION

A y Docket No. 16355-002500

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT** the specification of which X is attached hereto or was filed on as Application Serial No. and was amended on (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

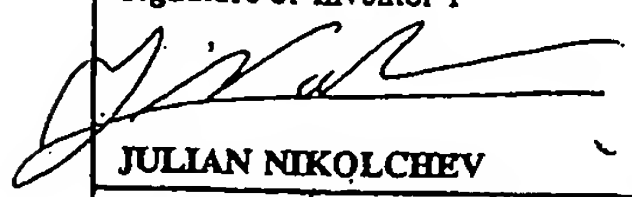
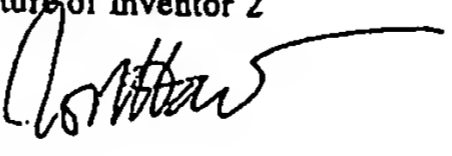
Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119
			Yes <u> </u> No <u> </u>
			Yes <u> </u> No <u> </u>

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Date of Filing	Status
		<u> </u> Patented <u> </u> Pending <u> </u> Abandoned
		<u> </u> Patented <u> </u> Pending <u> </u> Abandoned

Full Name of Inventor 1	Last Name <u>NIKOLCHEV</u>	First Name <u>JULIAN</u>	Middle Name or Initial
Residence & Citizenship	City <u>Portola Valley</u>	State/Foreign Country <u>California CA</u>	Country of Citizenship <u>United States of America</u>
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Full Name of Inventor 2	Last Name <u>TON</u>	First Name <u>DAI</u>	Middle Name or Initial
Residence & Citizenship	City <u>San Jose</u>	State/Foreign Country <u>California CA</u>	Country of Citizenship <u>United States of America</u>
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Full Name of Inventor 3	Last Name <u>///</u>	First Name	Middle Name or Initial
Residence & Citizenship	City	State/Foreign Country	Country of Citizenship
Post Office Address	Post Office Address	City	State/Country Zip Code

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1  JULIAN NIKOLCHEV	Signature of Inventor 2  DAI TON	Signature of Inventor 3 ///
Date <u>6/7/95</u>	Date <u>6/7/95</u>	Date

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN

Applicant or Patentee: JULIAN NIKOLCHEV and DAI TON
Serial or Patent No.: _____
Filed or Issued: _____
Title: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION
DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT

I hereby declare that I am

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN CONCEPTUS, INC.
ADDRESS OF SMALL BUSINESS CONCERN 1021 Howard Avenue, San Carlos, California 95131

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT by inventor(s) JULIAN NIKOLCHEV and DAI TON described in

- ☒ the specification filed herewith
☐ application Serial No. _____, filed _____
☐ Patent No. _____, issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____
ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME _____
ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Julian Nikolchev
TITLE OF PERSON IF OTHER THAN OWNER V.P.
ADDRESS OF PERSON SIGNING 1021 Howard Avenue, San Carlos, California 94070

SIGNATURE [Signature] DATE 6/2/95

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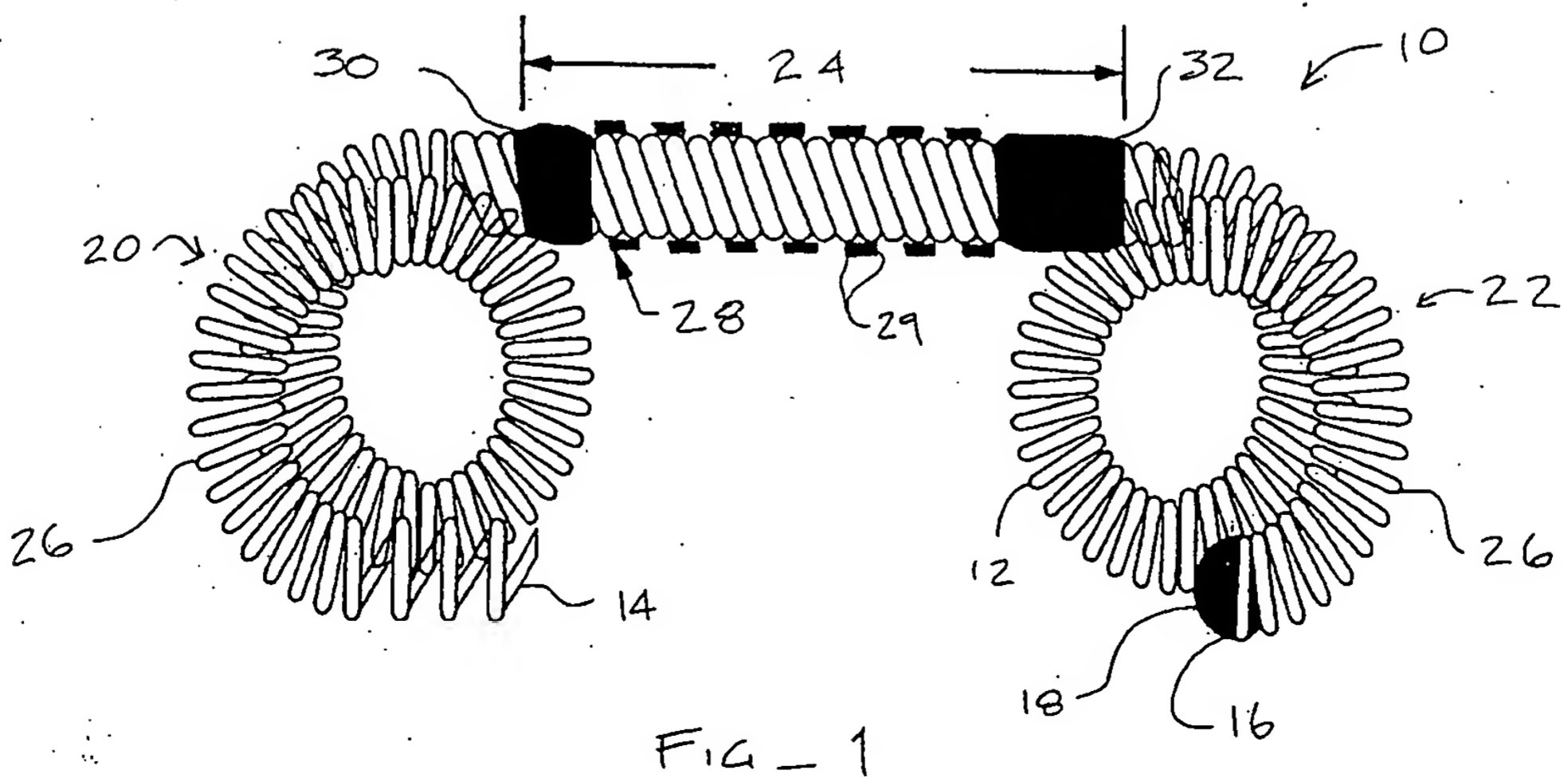
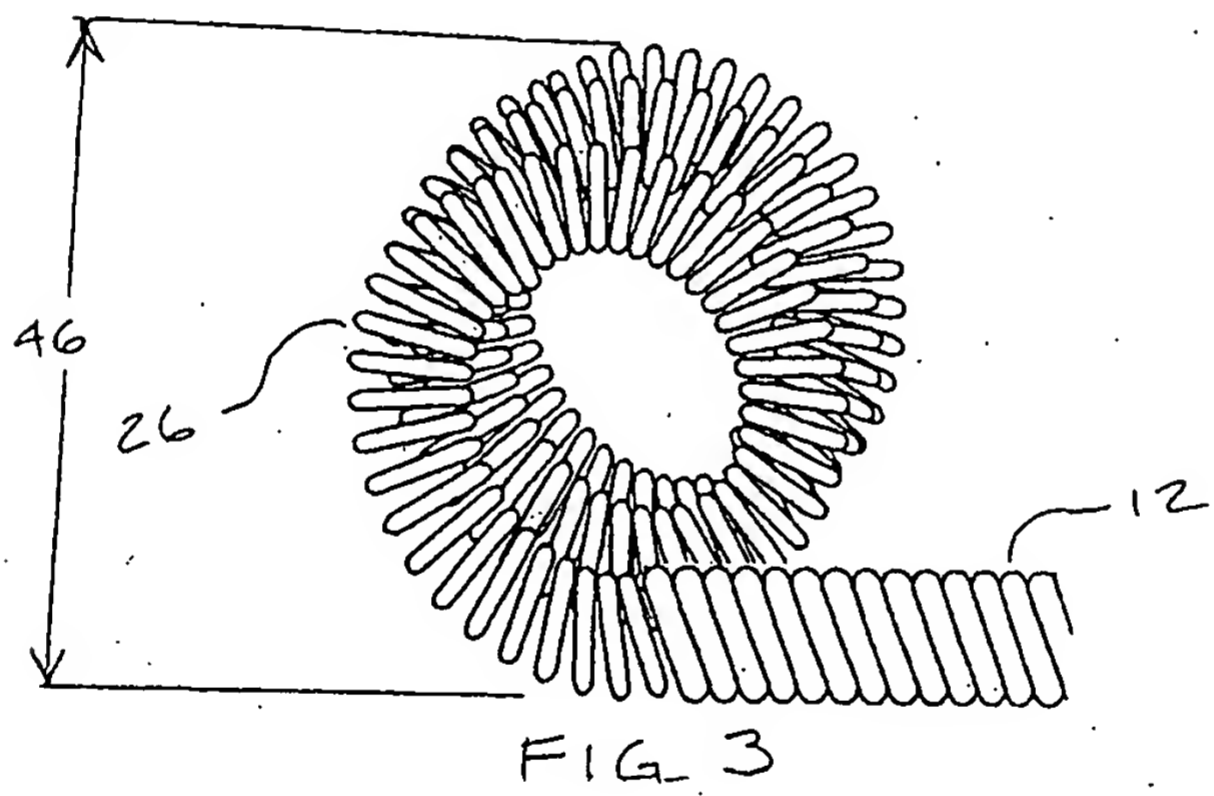
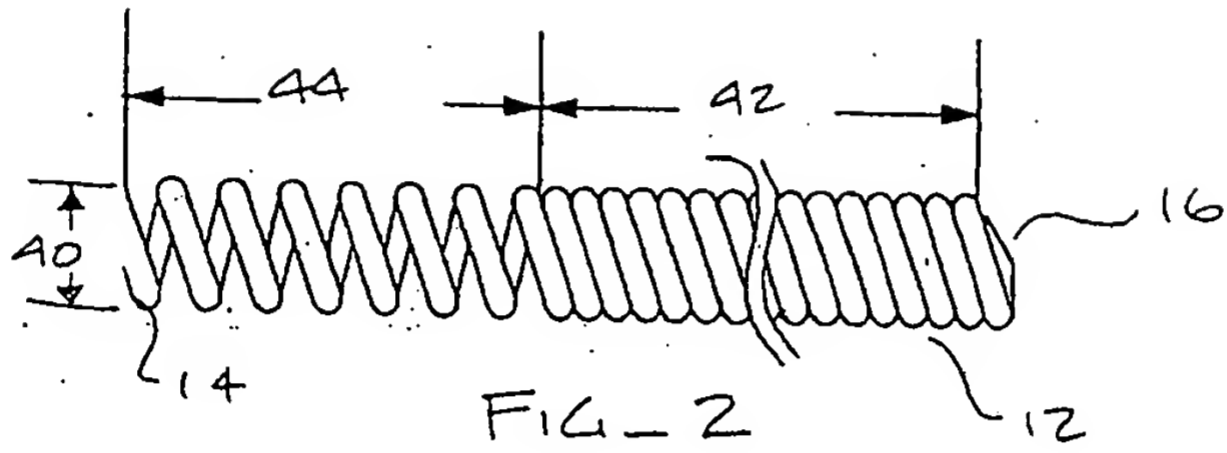


FIG-4

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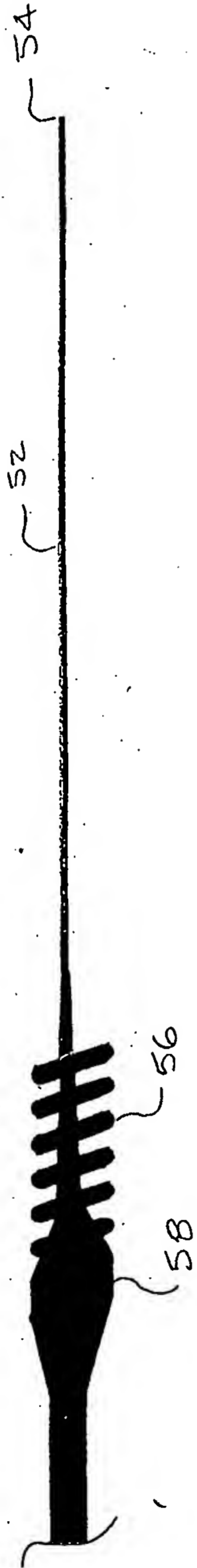


FIG-5

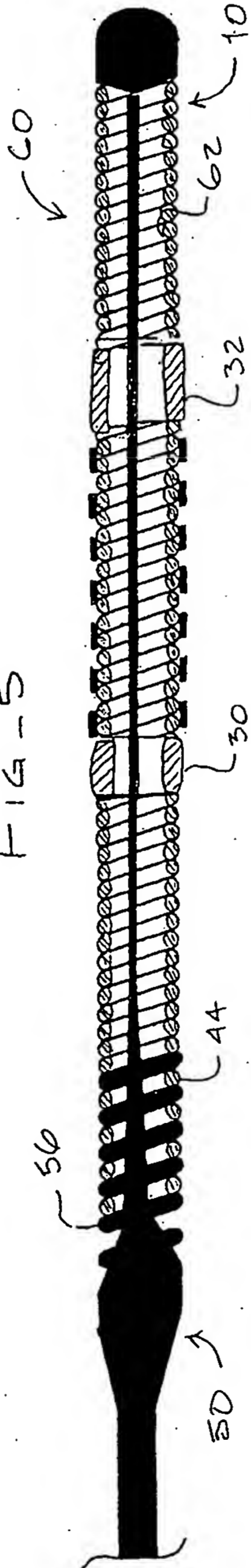
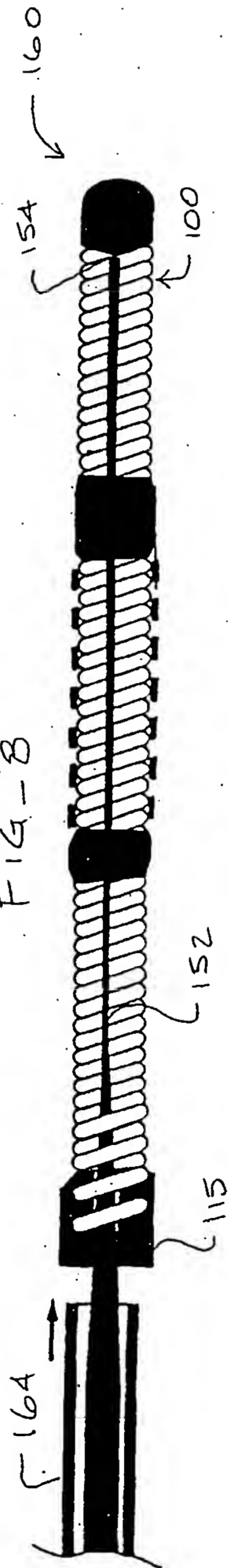


FIG-8



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FIG-7

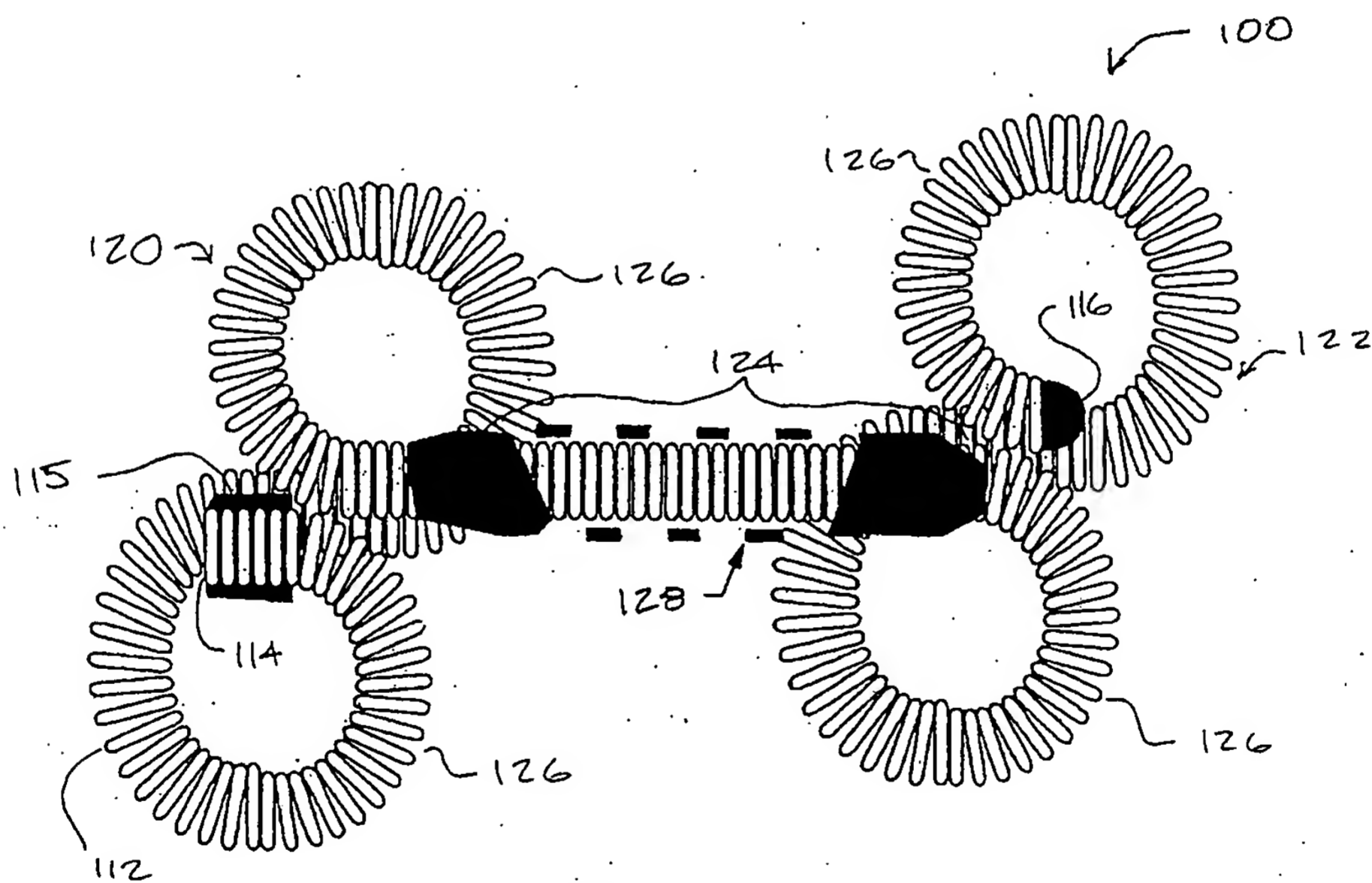
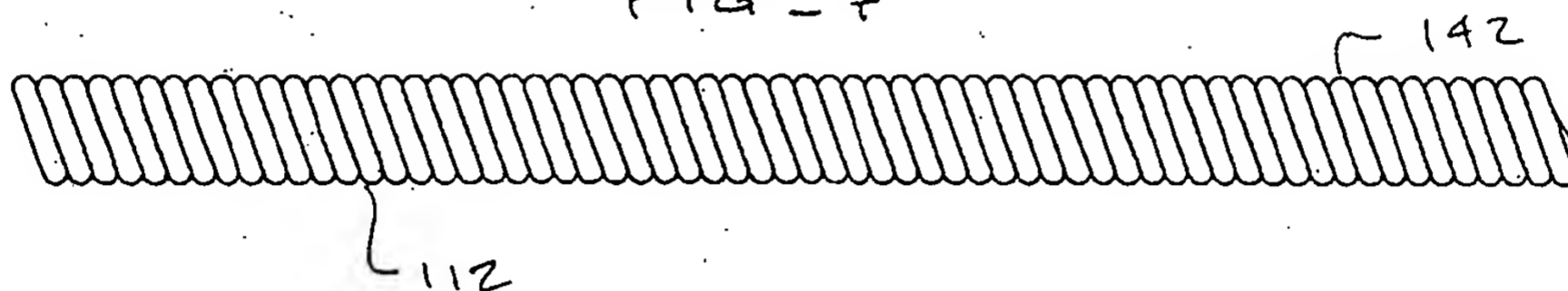
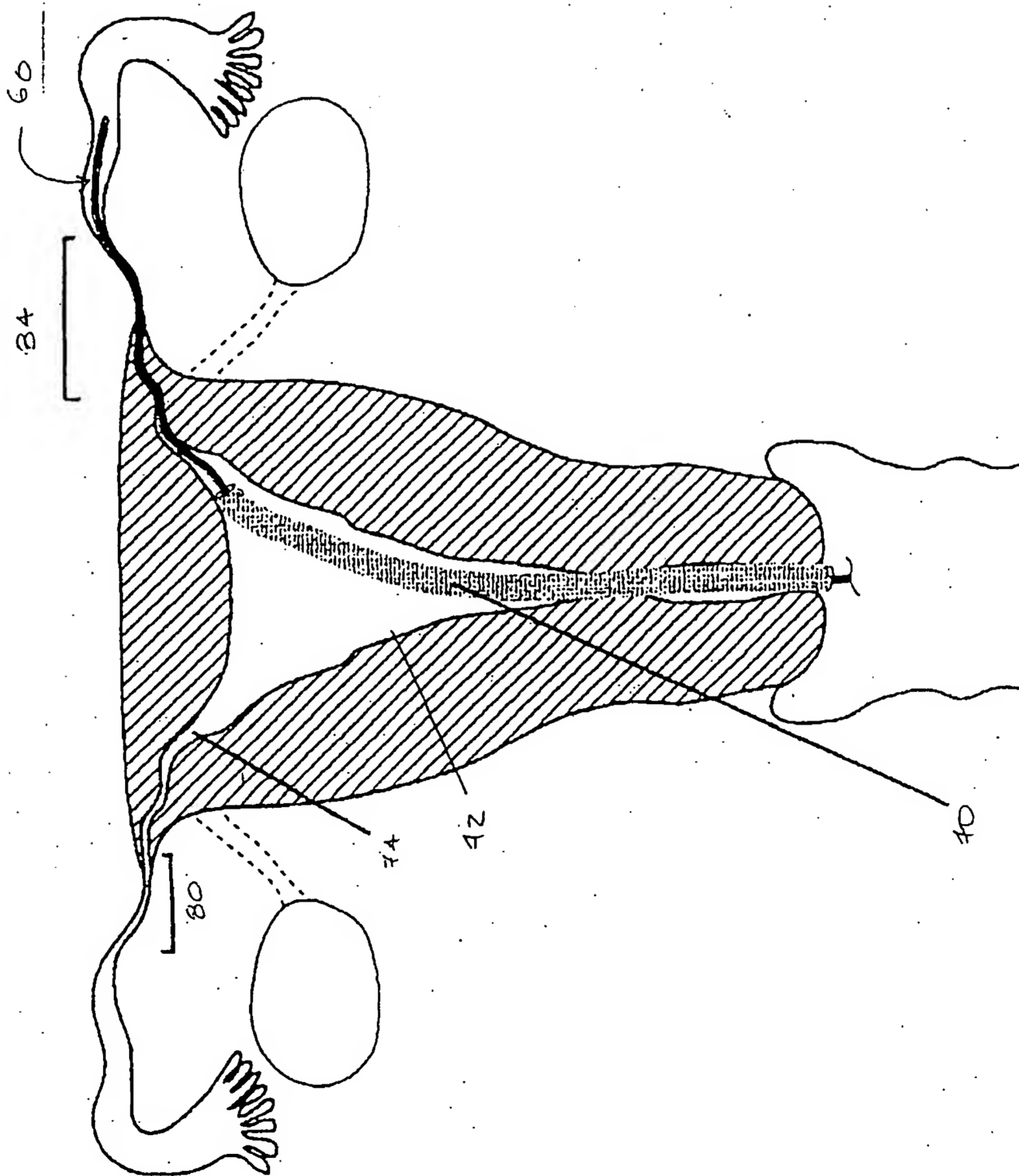


FIG-6

6355-25
SH 4 OF 5

08/475252

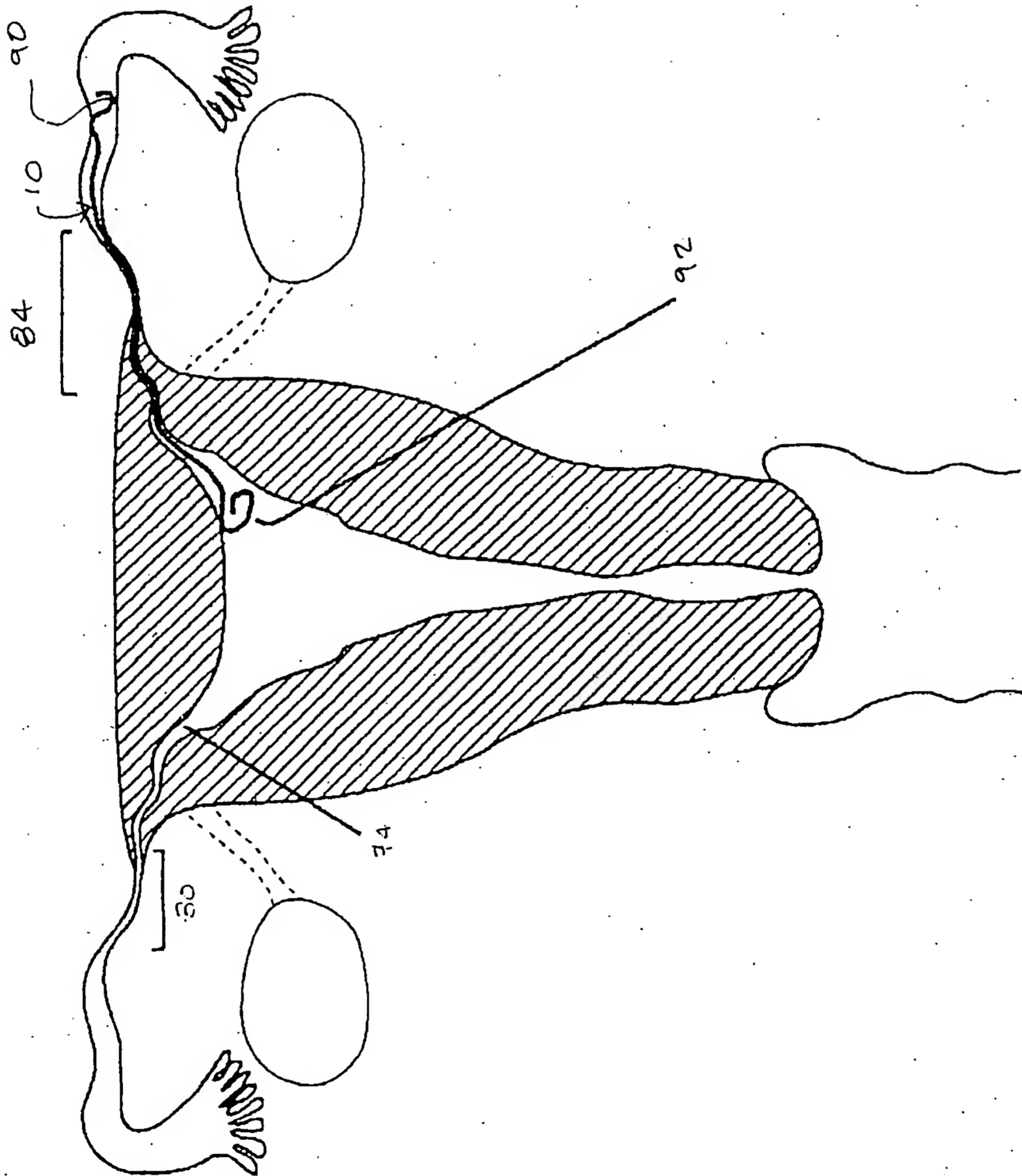
FIG-9



11 355-25
E. 5 OF 5

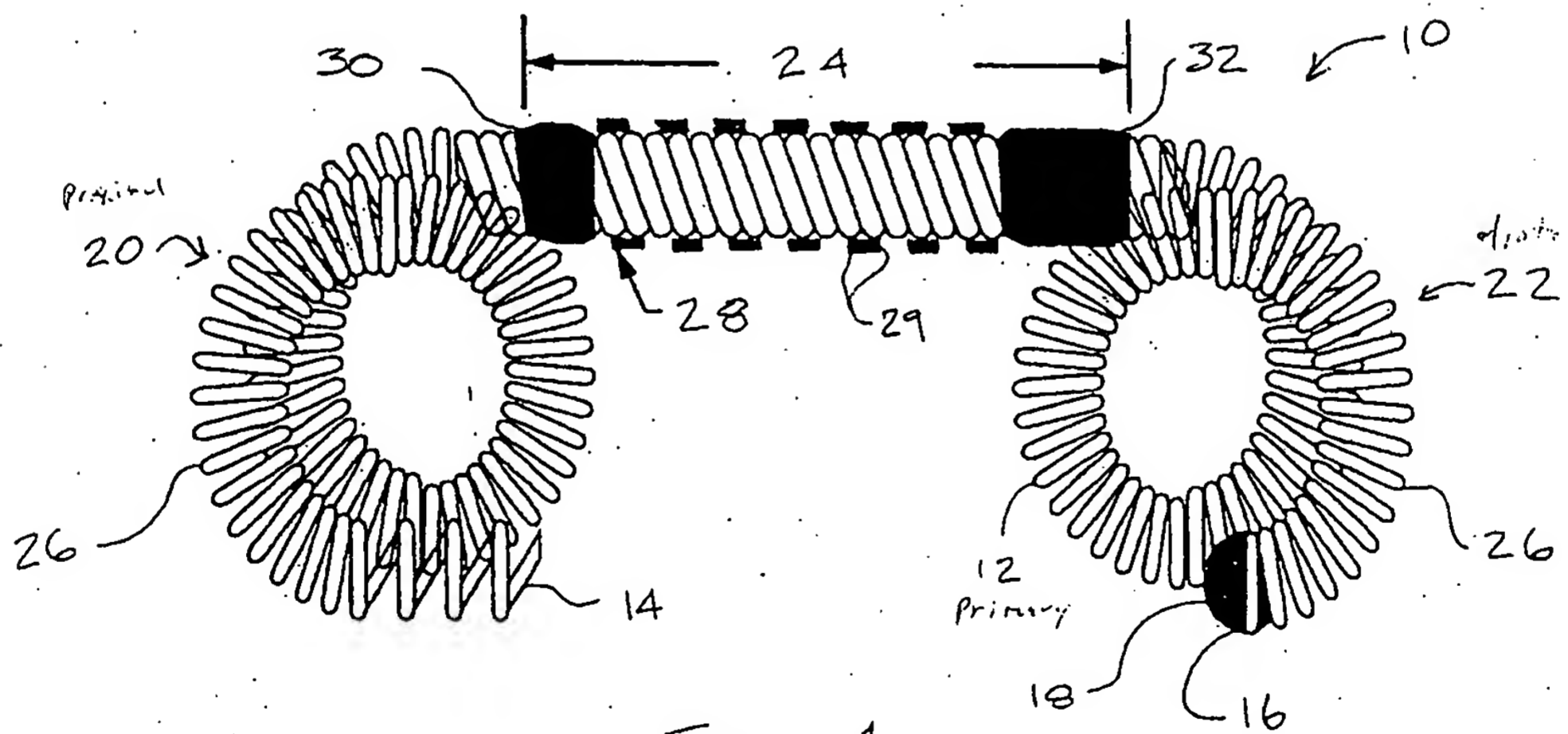
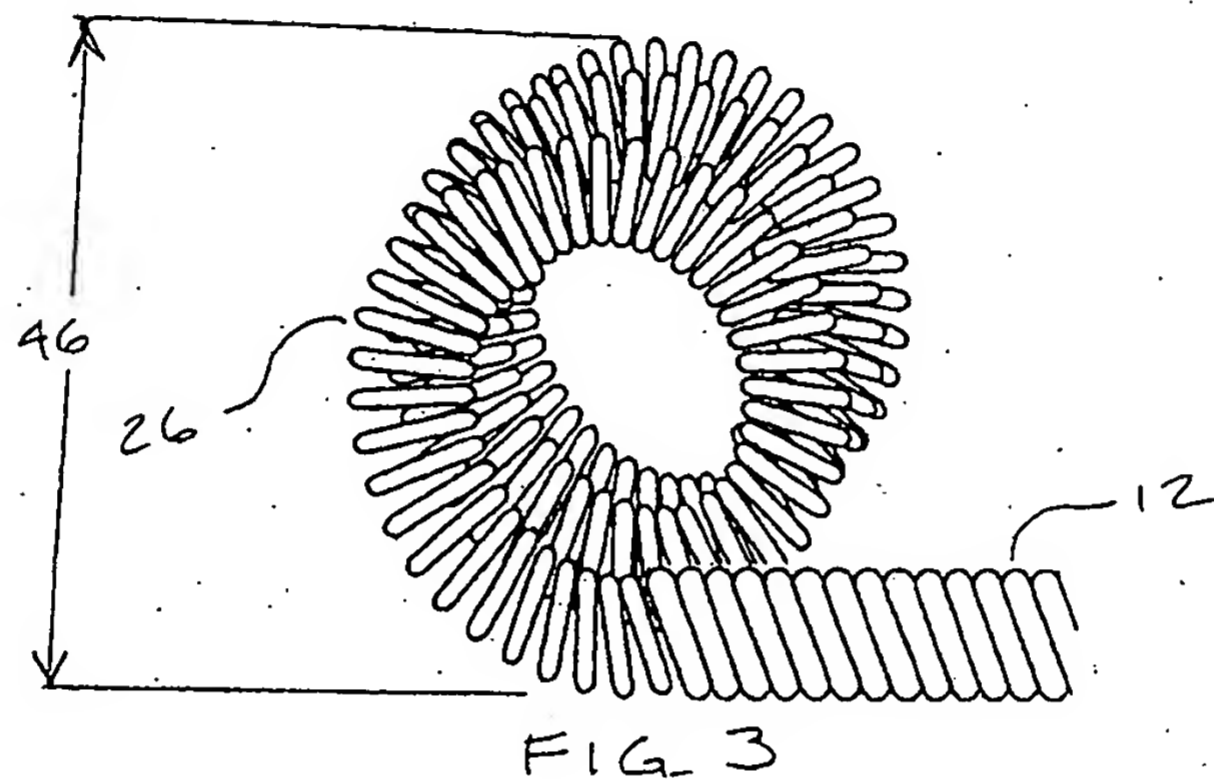
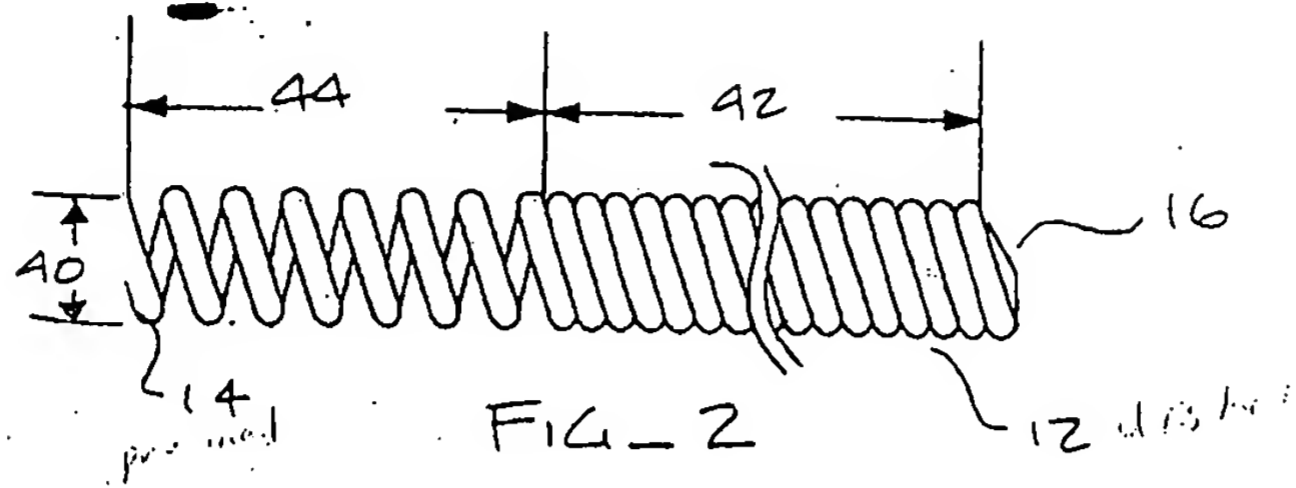
08/475252

FIG-10



08/475252
5-1
330

128
831



4,34

1-2, 3-6

1-2, 3-6

34-38

08/475252

FIG-4

50



FIG-5

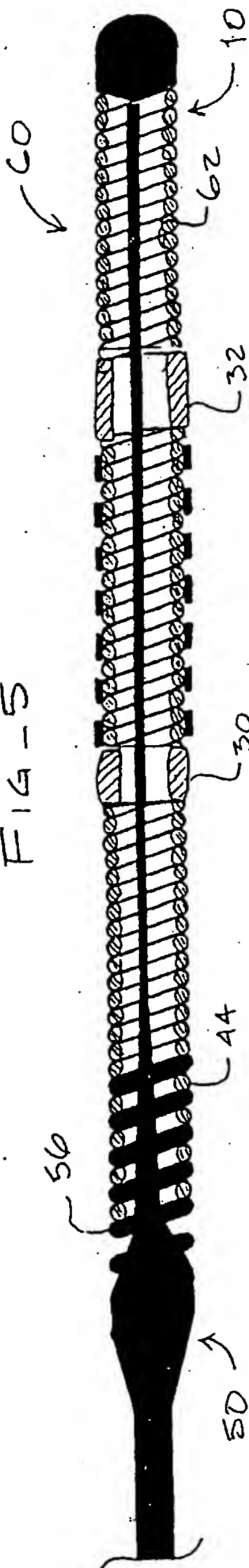


FIG-8

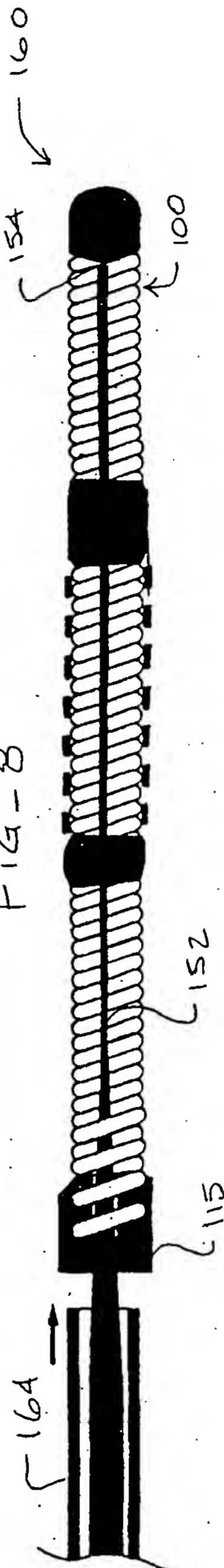


FIG - 7

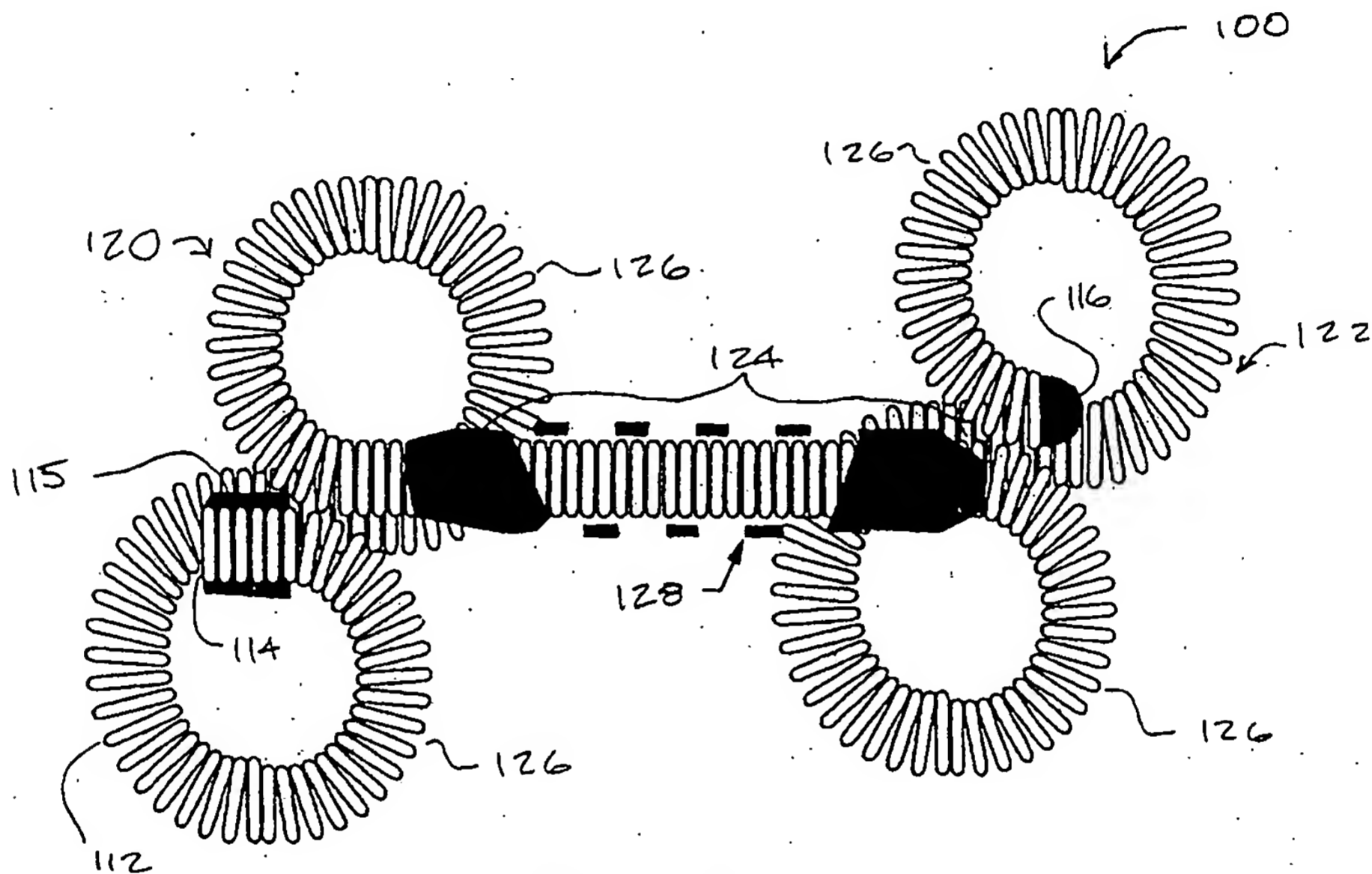
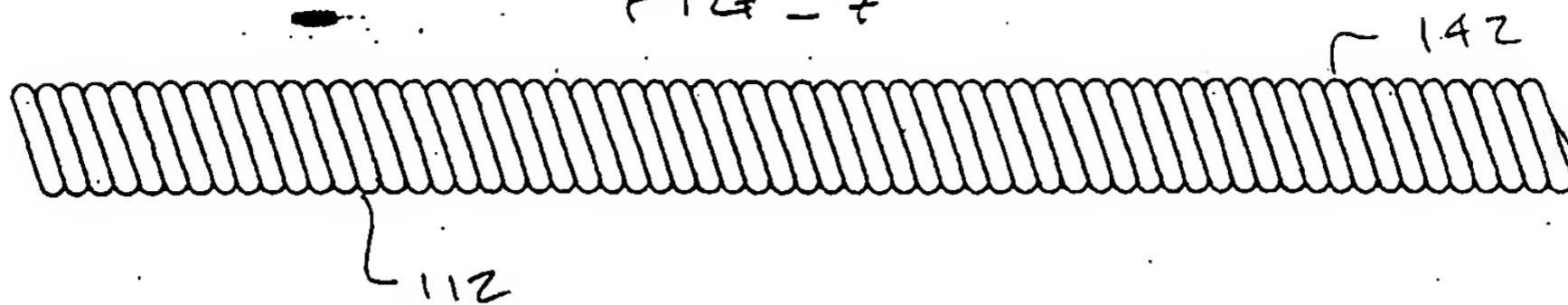
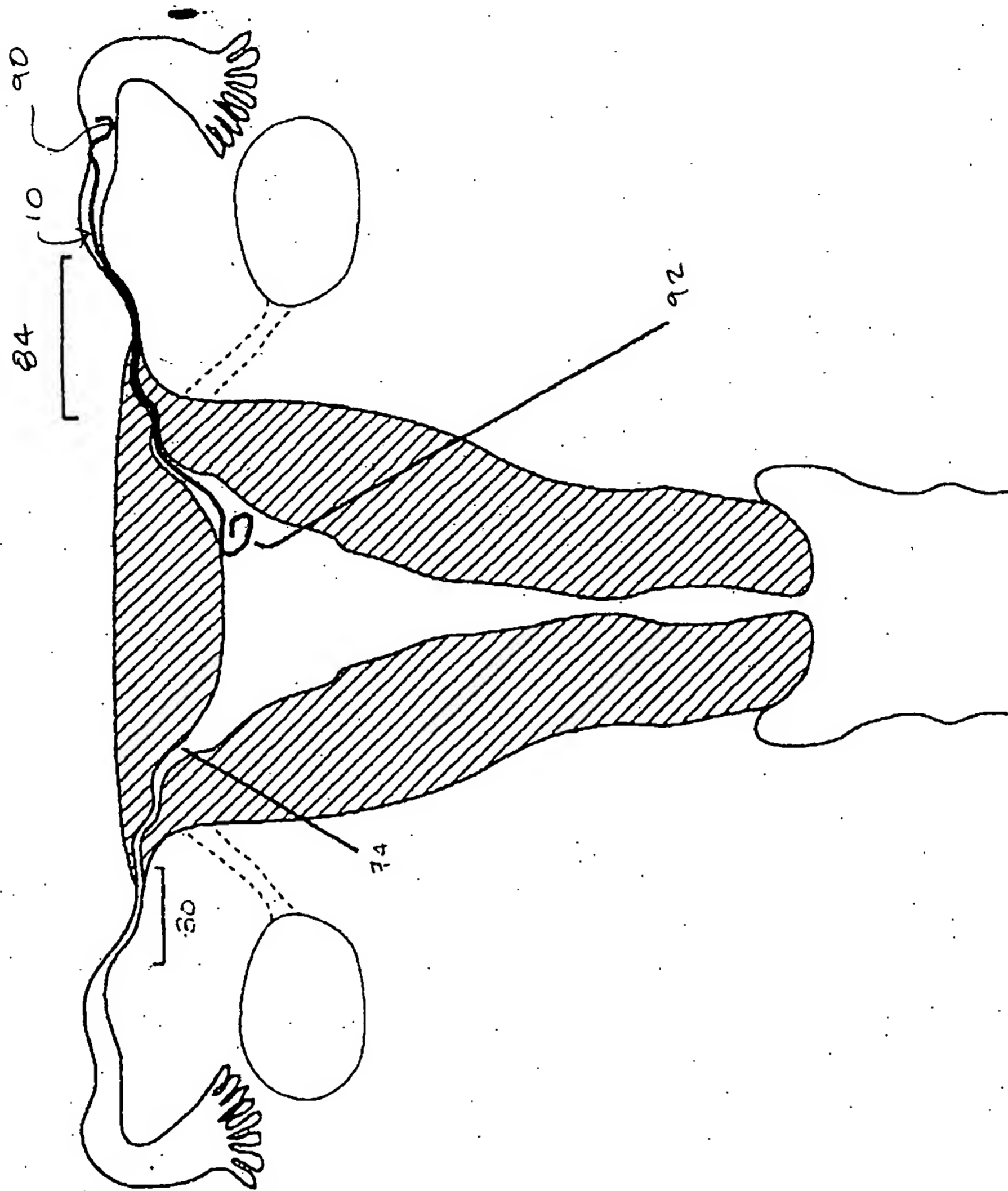


FIG - 6

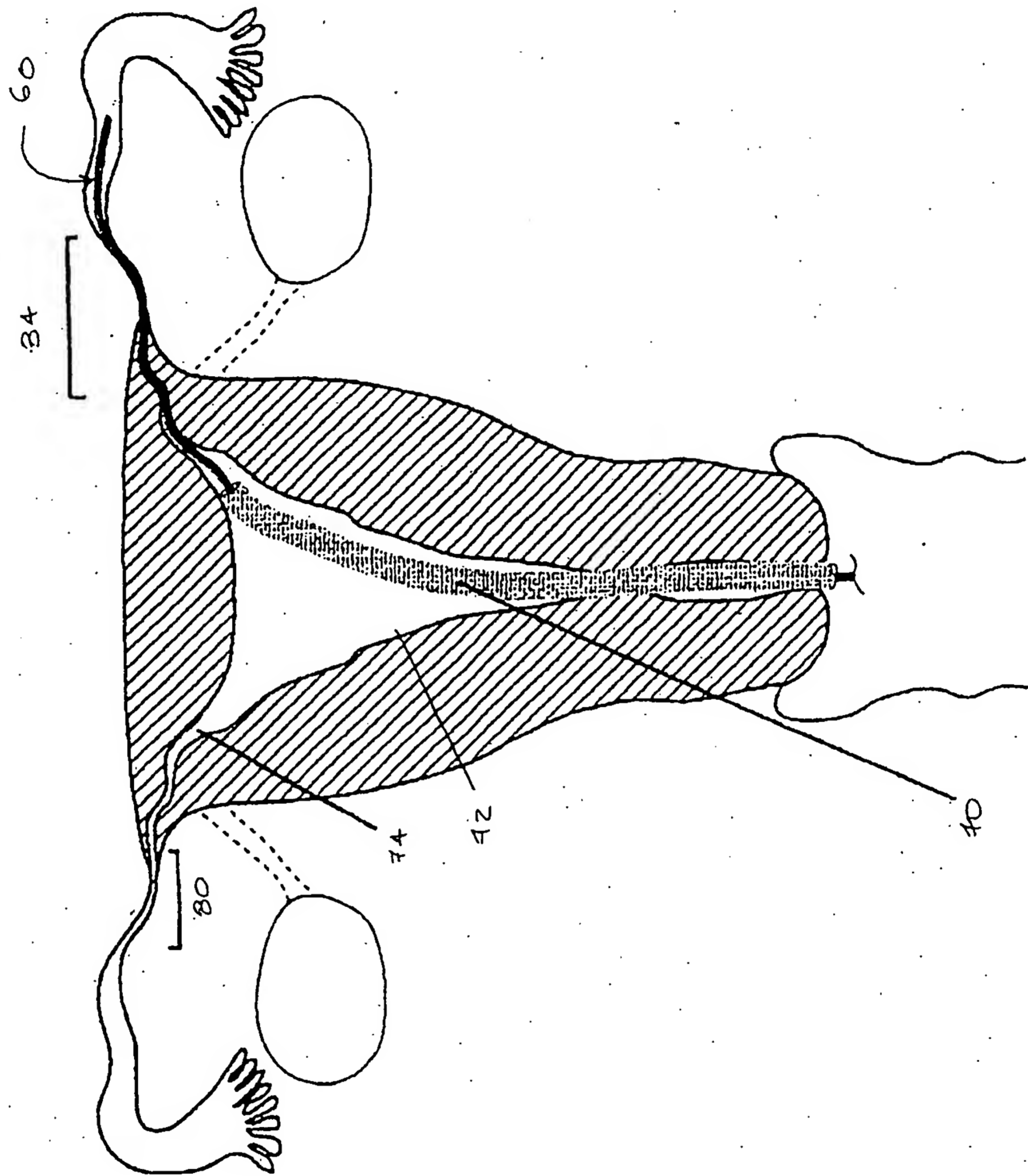
08/475252

FIG-10



08/475252

FIG-9



CON '323 Patent
(1997)



US006705323B1

(12) **United States Patent**
Nikolchev et al.

(10) **Patent No.:** US 6,705,323 B1
(45) **Date of Patent:** *Mar. 16, 2004

(54) **CONTRACEPTIVE TRANSCERVICAL
FALLOPIAN TUBE OCCLUSION DEVICES
AND METHODS**

(75) **Inventors:** Julian N. Nikolchev, Portola Valley;
Dai T. Ton, San Jose; Ashish Khera,
San Francisco; Donnell W. Gurskis,
Pleasanton; Steven Bacich, Half Moon
Bay, all of CA (US)

(73) **Assignee:** Conceptus, Inc., San Carlos, CA (US)

(*) **Notice:** This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) **Appl. No.:** 09/093,835

(22) **Filed:** Jun. 8, 1998

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/474,779, filed on Jun. 7, 1995, now Pat. No. 6,176,240, and a continuation-in-part of application No. 08/475,252, filed on Jun. 7, 1995, now abandoned.

(60) Provisional application No. 60/059,861, filed on Sep. 24, 1997.

(51) **Int. Cl.⁷** A61F 6/06

(52) **U.S. Cl.** 128/830; 128/831

(58) **Field of Search** 128/830-841

(56) **References Cited**

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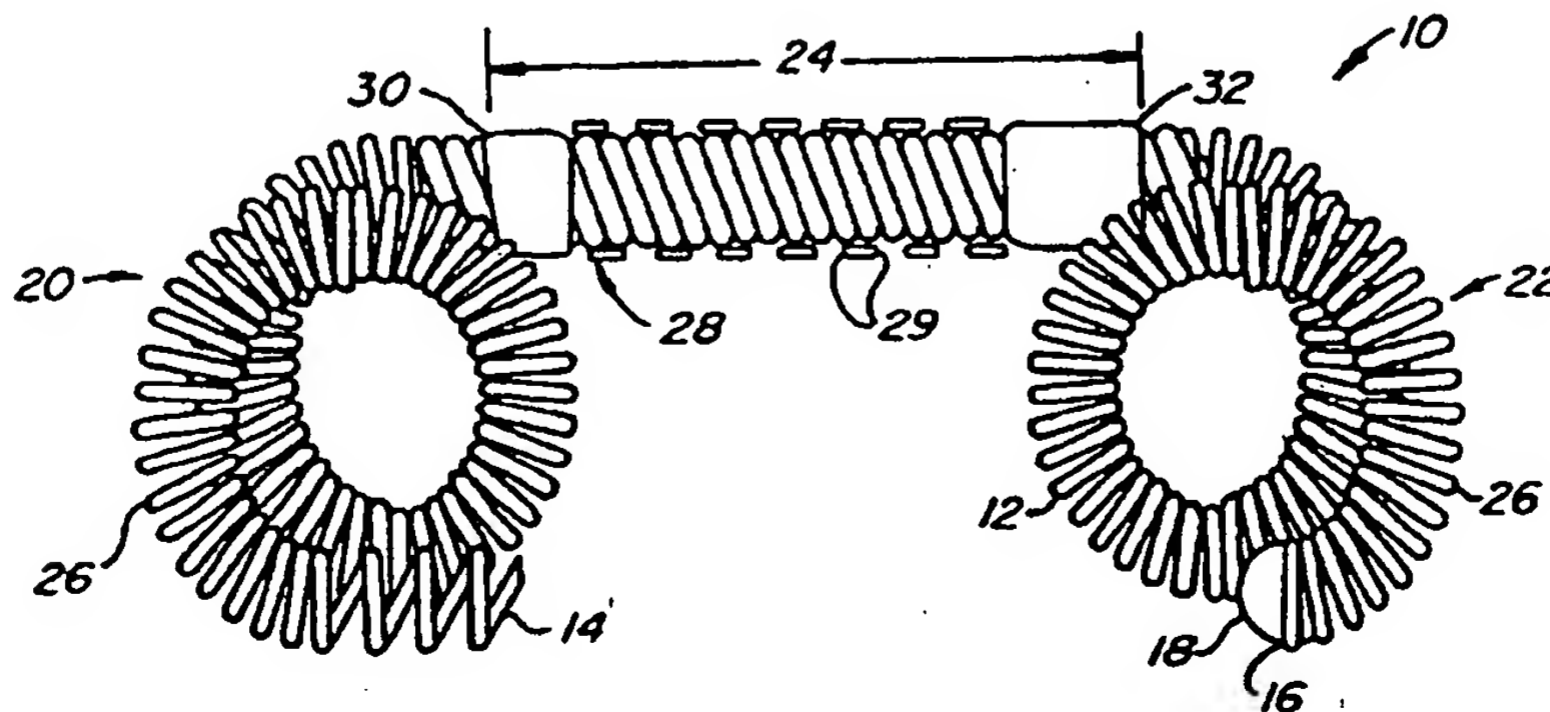
Primary Examiner—Michael A. Brown

(74) **Attorney, Agent, or Firm**—Townsend and Townsend and Crew LLP; Mark D. Barrish, Esq.

(57) **ABSTRACT**

The invention provides intrafallopian devices and non-surgical methods for their placement to prevent conception. The efficacy of the device is enhanced by forming the structure at least in part from copper or a copper alloy. The device is anchored within the fallopian tube by a lumen-traversing region of the resilient structure which has a helical outer surface, together with a portion of the resilient structure which is biased to form a bent secondary shape, the secondary shape having a larger cross-section than the fallopian tube. The resilient structure is restrained in a straight configuration and transcervically inserted within the fallopian tube, where it is released. Optionally, permanent sterilization is effected by passing a current through the resilient structure to the tubal walls.

81 Claims, 13 Drawing Sheets



AMS '504 Patent
(1996)



US007073504B2

(12) **United States Patent**
Callister et al.

(10) **Patent No.:** **US 7,073,504 B2**
(45) **Date of Patent:** ***Jul. 11, 2006**

(54) **CONTRACEPTIVE SYSTEM AND METHOD OF USE**

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(Continued)

Primary Examiner—Henry Bennett

Assistant Examiner—Andrea M. Ragonese

(74) *Attorney, Agent, or Firm*—Barbara A. Wrigley; Oppenheimer Wolff & Donnelly LLP; José W. Jimenez

(57) **ABSTRACT**

A device and method of using the device for contraception or sterilization and particularly for reversible contraception by occluding a reproductive lumen to prevent the passage of reproductive cells through the lumen for a desired period of time until the patient wishes to become fertile again and then be reopened. The occluding member preferably comprises a tubular framework formed from a shape memory material configured to be implanted in a reproductive lumen. The occluding member is implanted within a body lumen, secured to the wall of the reproductive lumen and then collapsed to collapse the wall and occlude the lumen. Alternatively, the occluding member may be collapsed upon a solid plug. The closure of the reproductive lumen may be reversed by introducing a balloon catheter and by a series of inflations of the balloon reexpanding the collapsed occluding member or by removing the plug. The occluding member and the plug may be configured to facilitate endothelialization, to provoke an inflammatory responses or to deliver a drug.

(75) **Inventors:** Jeffrey P. Callister, Menlo Park, CA (US); William S. Tremulis, Redwood City, CA (US); Denise S. Harges, Salt Lake, UT (US)

(73) **Assignee:** AMS Research Corporation, Minnetonka, MN (US)

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) **Appl. No.:** 08/770,123

(22) **Filed:** Dec. 18, 1996

(65) **Prior Publication Data**

US 2002/0013589 A1 Jan. 31, 2002

(51) **Int. Cl.**
A61F 6/06 (2006.01)

(52) **U.S. Cl.** 128/831; 128/830

(58) **Field of Classification Search** 604/96, 604/104, 106-109, 515, 93.01, 96.01, 174-175, 604/264; 606/191-198, 135; 623/1, 1.1, 623/1.11, 1.12, 1.15, 1.22, 902-903; 128/830-831
See application file for complete search history.

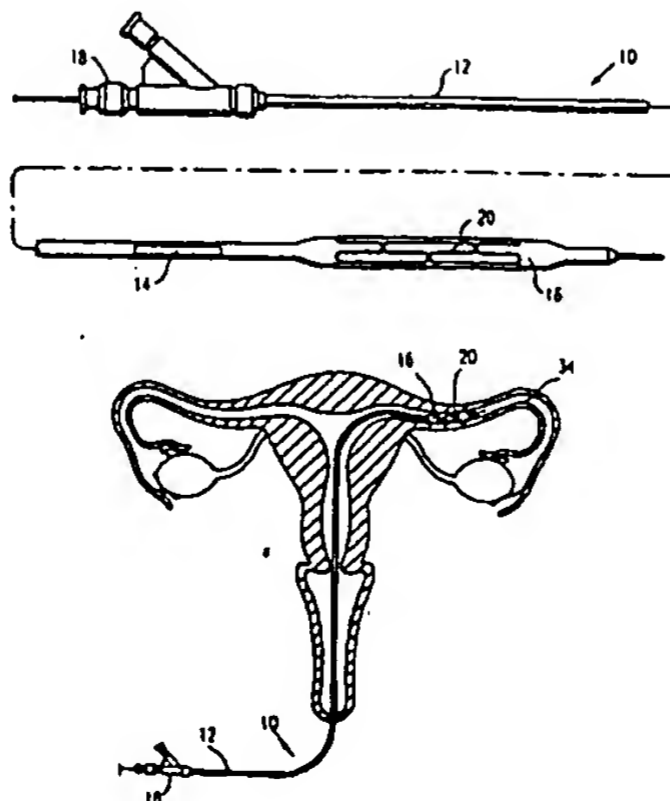
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72 Claims, 5 Drawing Sheets



AMS '052 Patent
(1998)



US006096052A

United States Patent [19]

Callister et al.

[11] Patent Number: 6,096,052

[45] Date of Patent: Aug. 1, 2000

[54] OCCLUDING DEVICE AND METHOD OF USE

[75] Inventors: Jeffrey P. Callister, Menlo Park;
William S. Tremulis, Redwood City,
both of Calif.

[73] Assignee: Ovion, Inc., Redwood City, Calif.

[21] Appl. No.: 09/112,085

[22] Filed: Jul. 8, 1998

[51] Int. Cl.⁷ A61B 6/20; A61B 6/22

[52] U.S. Cl. 606/157; 606/108

[58] Field of Search 606/157, 158,
606/108

[56] References Cited

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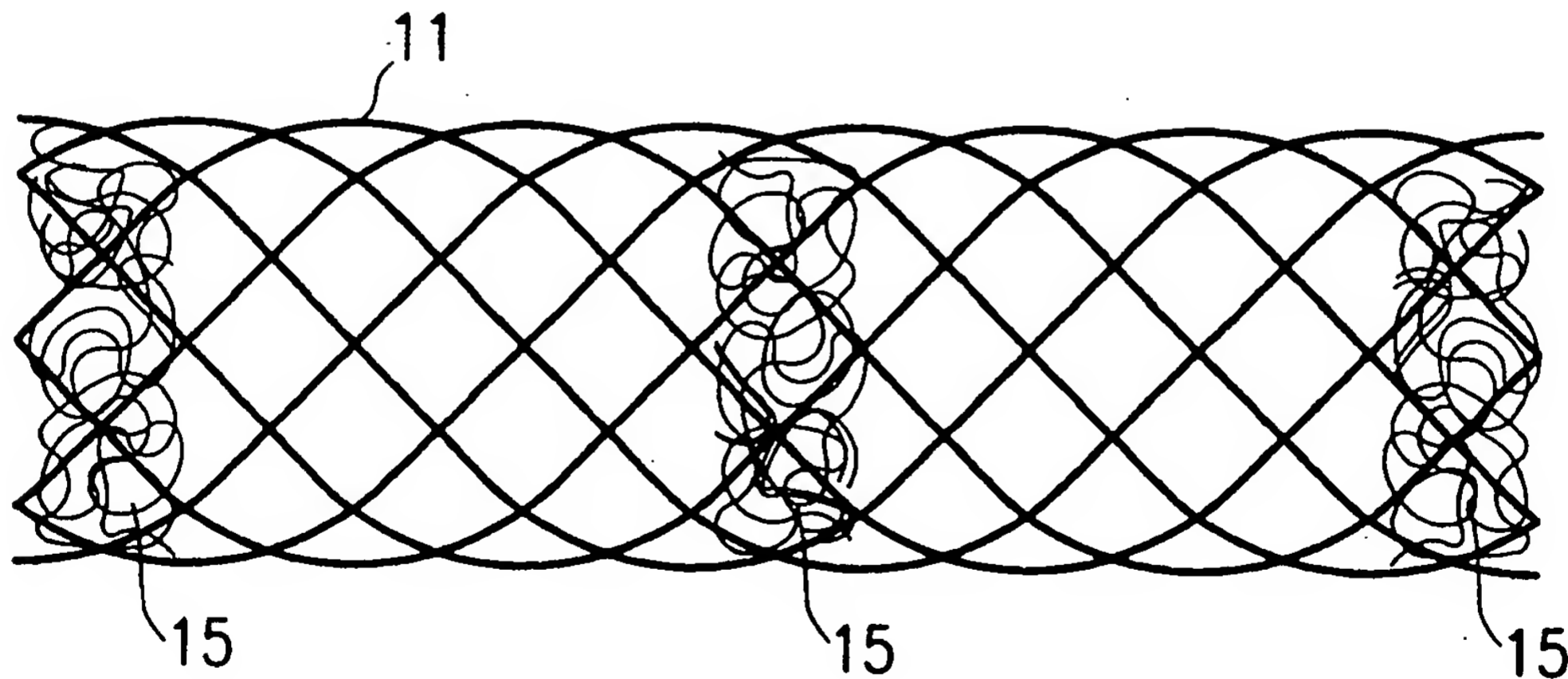
0 105 669	4/1984	European Pat. Off.
WO 94/24944	11/1994	WIPO

Primary Examiner—Paul J. Hirsch
Attorney, Agent, or Firm—Heller Ehrman White & McAuliffe

[57] ABSTRACT

A device for occluding a body lumen, and particularly contraceptive or sterilization device for occluding a reproductive tract or lumen to prevent the passage of reproductive cells through the tract or lumen, generally comprising a tubular member, and a mesh member, transversely disposed on the tubular member lumen. The mesh member is permeable to allow for tissue ingrowth, which produces a tissue impregnated mesh occluding the body lumen. The occluding device of the invention can be used in the fallopian tubes of a female patient, the vas deferens of a male patient, or other body lumen.

42 Claims, 9 Drawing Sheets



AMS '116 Patent
(1998)



US006432116B1

(12) **United States Patent**
Callister et al.

(10) Patent No.: **US 6,432,116 B1**
(45) Date of Patent: ***Aug. 13, 2002**

(54) **OCCCLUDING DEVICE AND METHOD OF USE**

(75) Inventors: **Jeffrey P. Callister, Menlo Park;**
William S. Tremulis, Redwood City,
both of CA (US)

(73) Assignee: **Ovion, Inc., Redwood City, CA (US)**

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/468,749**

(22) Filed: **Dec. 21, 1999**

Related U.S. Application Data

(63) Continuation of application No. 09/112,085, filed on Jul. 8, 1998, now Pat. No. 6,096,052.

(51) Int. Cl.⁷ **A61F 6/20; A61F 6/22**

(52) U.S. Cl. **606/157; 606/108**

(58) Field of Search **606/157, 158,**
606/108

(56) **References Cited**

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5,382,261 A	1/1995	Palmaz	606/158
5,423,849 A	6/1995	Engelson et al.	606/191
5,443,500 A	8/1995	Sigwart	623/1
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WO	WO 98/26737	6/1998
WO	WO 99/15116	4/1999

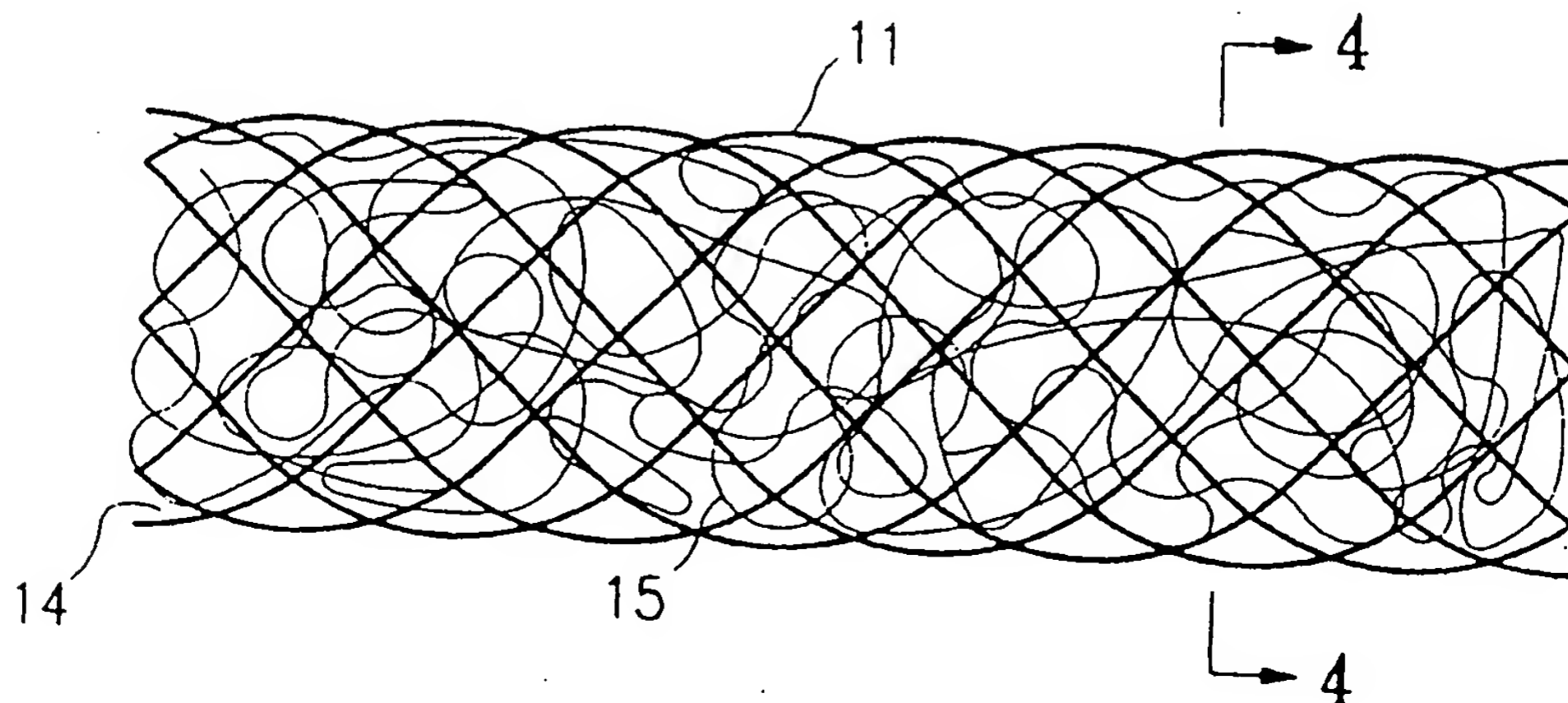
Primary Examiner—Paul J. Hirsch

(74) Attorney, Agent, or Firm—Heller Ehrman White & McAuliffe

(57) **ABSTRACT**

A device for occluding a body lumen, and particularly contraceptive or sterilization device for occluding a reproductive tract or lumen to prevent the passage of reproductive cells through the tract or lumen, generally comprising a tubular member, and a mesh member, transversely disposed on the tubular member lumen. The mesh member is permeable to allow for tissue ingrowth, which produces a tissue impregnated mesh occluding the body lumen. The occluding device of the invention can be used in the fallopian tubes of a female patient, the vas deferens of a male patient, or other body lumen.

45 Claims, 9 Drawing Sheets



'298 Office Action



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,298	06/20/2003	Julian N. Nikolchev	016355-002580US	6671
7590	07/19/2006		EXAMINER	
James Scheller, Esq. Blakely Sokoloff Taylor & Zafman LLP 1279 Oakmead Parkway Sunnyvale, CA 94085			BENNETT, HENRY A	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,298	NIKOLCHEV ET AL.	
	Examiner	Art Unit	
	Henry Bennett	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-81 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-21 is/are allowed.
- 6) ☒ Claim(s) 22-81 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date ____.

- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Henry Bennett
 Supervisor Patent Examiner
 Group 3700

Art Unit: 3743

After reviewing of the file history of the present application, It has been determined that the effective date for claims 22-81 in the present application is September 24, 1997 which corresponds to the filing date of applicants provisional application 60/059861. A key factor in making this decision was the review of applicants prior applications 08/474229 (now US Patent 6176240) and application 08/475252 which have an effective filing date of June 07, 1995 and provisional application 60/059861 which has an effective date of September 24, 1997.

Claims 24 and 81 in the present application are representative of the critical limitations on which the effective filing date of claims 22-81 was decided.

Claim 24 (Previously Presented) A contraceptive device, comprising

a) a tubular body which is expandable from a first tubular configuration to a second larger tubular configuration to facilitate securing at least a portion of the tubular body to a wall portion defining at least in part a lumen of a patient's reproductive system and which has an open framework facilitating the in growth of tissue cells; a member within the expandable tubular body which is configured to support tissue growth.

Claim 81. (New) A contraceptive device, comprising

a) a body expandable within a lumen of a patient's reproductive system from

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a first tubular configuration to a second tubular configuration, the second tubular configuration having a larger cross-sectional profile than the first tubular configuration relative to an axis of the contraceptive device to facilitate securing at least a portion of the body to a wall portion defining at least in part a lumen of a patient's reproductive system, the body comprising a helical coil and allowing the in growth of tissue

b) a material disposed at least in part within the expandable body so as to incite tissue in-growth.

Applicant has asserted that he has a basis for all of the limitation recited of claims 24 and 81 in his prior applications 08/474229 (now US Patent 6176240) and application 08/475252. After a careful review of these applications, it has been determined that applicant has a basis for a contraceptive device that expands from a first to a larger configuration but he does not have a basis for "a contraceptive device that has a first tubular configuration and expands to a second larger configuration about an axis of the contraceptive device" or "expansion from a first tubular configuration to a second larger tubular configuration". The examiner is of the opinion that in applicants prior applications and patent, the disclosed contraceptive device does in fact expand in size but it does not expand about a tubular axis of the contraceptive device to lodge itself in the reproductive tract. It has also been determined that in the in applicants previous disclosures in 08/474229 (now US Patent 6176240) and

Art Unit: 3743

application 08/475252, the inner diameter of the initial tubular member appears to remain the same in the expansion to the second larger tubular configuration. These limitations are critical to applicants assertion that he has a basis for claims 24 and 81 in his prior disclosures. It appears that a proper interpretation of applicant claims to **"expansion to a larger tubular configuration"** should be evaluated in light of applicants previous disclosures which supports a larger configuration but not a larger tubular configuration where the inside diameter of the first tubular members is increased as a result of the expansion.

It is also important to note that in claim 81 it is not clear which "axis" applicant is referring to. It is presumed to be the longitudinal axis given that this interpretation would result in the securing of the tubular contraceptive device to the wall of the reproductive lumen passage.

In light of the above positions taken by the examiner the following rejections now apply

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 81 recites "an axis of the contraception device" This limitation is considered or to be indefinite in that the exact an about which the device expands has not been specified.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Given that it has been determined by the examiner that claims 22-81 have an effective filing date of September 24, 1997, the following rejection applies

2. Claims 22-81 rejected under 35 U.S.C. 102(e) as being Anticipated by Callister et al. **US 7073504**.

Callister et al discloses A contraceptive device, in Figs 1-18 that comprises
a) a body expandable within a lumen of a patient's reproductive system from a first tubular configuration to a second tubular configuration, the second tubular configuration having a larger cross-sectional profile than the first tubular configuration relative to an axis of the contraceptive device to facilitate securing at least a portion of the body to a wall portion defining at least in part a lumen of a patient's reproductive system, the body comprising a helical coil and allowing the in growth of tissue

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b) a material disposed at least in part within the expandable body so as to incite tissue in-growth.

Claims 12-21 are allowable.

Should applicant decided to provoke an interference with application 08/770123 (now US Patent 7073504) please consider procedures set forth in MPEP 2304 for the most recent requirements.

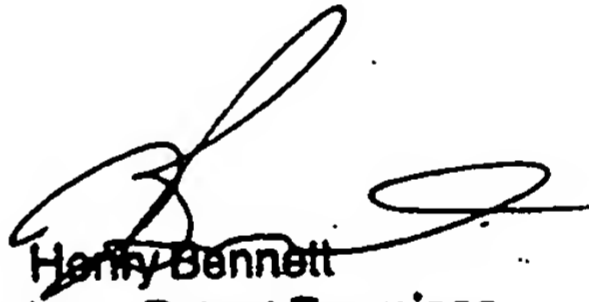
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry Bennett whose telephone number is 571-272-4791. The examiner can normally be reached on Monday through Friday from 8:00 am until 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennnett can be reached on (703) 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Henry Bennett
Supervisory Patent Examiner
Group 3700

Notice of References Cited	Application/Control No. 10/600,298	Applicant(s)/Patent Under Reexamination NIKOLCHEV ET AL.	
	Examiner Henry Bennett	Art Unit 3743	Page 1 of 1

U.S. PATENT DOCUMENTS

★		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
★	A	US-7,073,504	07-2006	Callister et al.	128/831
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

★		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

★		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

Copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

'298 Pending Claims

Pending Claims In App. No. 10/600,298

1-11. (Cancelled)

12. A contraceptive or sterilization device for occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising: a) a tubular member having a first end, a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and b) a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.

13. A contraceptive device installed within a lumen of the patient's reproductive system, comprising a) a tubular member having a first end, a second end, and a lumen extending therein, and having at least a portion thereof which is secured to a body wall portion defining at least in part the lumen of the patient's reproductive system; and b) an occluding member connected to the tubular member comprising an epithelialized mesh which occludes the lumen of the patient's reproductive system sufficiently to prevent the passage of reproductive cells therethrough.

14. A contraceptive system, comprising a) a catheter having a proximal end, a distal end, and a lumen extending at least in part therein; and b) a contraceptive device releasably connected to the catheter, having a tubular member having a first end, a second end, and a lumen extending therein, which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration, and having a mesh member connected to the tubular member, which is permeable to allow for tissue ingrowth to thereby occlude the reproductive body lumen.

15. A method of contraception comprising the steps of a) inserting within a desired body lumen a contraceptive device comprising a tubular member and a mesh member connected thereto; b) expanding the tubular member within the body lumen; c) securing the expanded tubular member to a wall portion defining at least in part the body lumen; and d) epithelializing the mesh member to occlude the body lumen.

16. The method of claim 15 wherein the step of expanding the tubular member comprises the step of releasing a radially compressive force on the tubular member.

17. The method of claim 16 wherein the contraceptive device is disposed within a lumen of a delivery catheter, and the step of releasing the radially compressive force comprises longitudinally displacing the tubular member out a distal end of the delivery catheter.

18. The method of claim 15 wherein the expanded tubular member is disposed within the body lumen for sufficient time for it to be epithelialized within the body lumen and thereby secured to the wall portion.

19. A contraceptive or sterilization device for occluding a fallopian tube to inhibit conception, comprising: a) a tubular structure having a first end, a second end, and a lumen extending therein, the tubular structure expandable within the fallopian tube from a first configuration to a second larger configuration; and b) a tissue ingrowth element connected to the tubular structure, the tissue ingrowth element inciting tissue ingrowth to thereby occlude the fallopian tube.

20. A contraceptive device installed within a patient's fallopian tube, comprising: a) a tubular structure having a first end, a second end, and a lumen extending therein, and having at least a portion thereof which is secured to a tubal wall portion of the patient's fallopian tube; and b) a tissue ingrowth element connected to the tubular structure comprising a material with tissue ingrowth therein which occludes the patient's fallopian tube sufficiently to disrupt conception.

21. A contraceptive system, comprising: a) a catheter having a proximal end, a distal end, and a lumen extending therein; and b) a contraceptive device releasably connected to the catheter, having a tubular structure having a first end, a second end, and a lumen extending therein, which is expandable within the reproductive body lumen from a first configuration to a second larger configuration, and having a tissue ingrowth element connected to the tubular structure, which is porous to allows for tissue ingrowth to thereby occlude the reproductive body lumen.

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22. A contraceptive device, comprising: a) a tubular body which is expandable from a first tubular configuration to a second larger tubular configuration having an expanded portion with an inner diameter within the tubular body which is larger than an inner diameter within the tubular body in the first configuration, the second configuration facilitating securing at least a portion of the tubular body to a wall portion defining at least in part a lumen of a patient's reproductive system, the tubular body having an open framework facilitating the ingrowth of tissue cells thereby securing the expanded portion of the tubular body to the wall portion of the reproductive system lumen, and b) a member within the tubular body which is configured to support tissue growth.

23. The contraceptive device of claim 22, wherein the member within the tubular body provokes an inflammatory response.

24. A contraceptive device, comprising, a) a tubular body which is expandable from a first tubular configuration to a second larger tubular configuration to facilitate securing at least a portion of the tubular body to a wall portion defining at least in part a lumen of a patient's reproductive system and which has an open framework

facilitating the ingrowth of tissue cells; b) a member within the expandable tubular body which is configured to support tissue growth.

25. A contraceptive device, comprising a) a tubular body which is expandable from a first tubular configuration to a second larger tubular configuration to facilitate securing at least a portion of the tubular body to a wall portion defining at least in part a lumen of a patient's reproductive system, the tubular body comprising a helical coil and allowing the ingrowth of tissue; b) a material disposed at least in part within the expandable tubular body so as to incite tissue in-growth.

26. A contraceptive device, comprising a tubular body which has a longitudinal axis, which is at least in part radially expandable about the longitudinal axis within a lumen of a patient's reproductive system from a first tubular configuration to a second tubular configuration having larger transverse dimensions than the first tubular configuration, which has an open structure in the expanded configuration for ingrowth of tissue cells for securing the expanded portion of the tubular body to a wall portion of the patient's reproductive system lumen, and which has a member within the tubular body which is configured for tissue growth.

27. A contraceptive device, comprising: a) a tubular body which has a longitudinal axis, which is at least in part radially expandable about the longitudinal axis within a lumen of a patient's reproductive system from a first tubular configuration to a second tubular configuration having larger transverse dimensions than the first tubular configuration to facilitate securing at least a portion of the tubular body to a wall portion defining at least in part a lumen of a patient's reproductive system and which has an open structure in the expanded configuration for ingrowth of tissue cells; and b) a member within the expandable tubular body which is configured for tissue growth.

28. The contraceptive device of claim 26 wherein the tubular member comprises a tube having a pattern of slots to allow the tubular member to be expanded to the open structure.

29. The contraceptive device of claim 26 wherein the tubular member is formed of a helical wire configured to allow the tubular member to be expanded to the open structure.

30. The contraceptive device of claim 26 wherein the tubular member comprises braided filaments configured to allow the tubular member to be expanded to the open structure.

31. The contraceptive device of claim 27 wherein the tubular member comprises a tube having a pattern of slots to allow the tubular member to be expanded to the open structure.

32. The contraceptive device of claim 27 wherein the tubular member is formed of a helical wire configured to allow the tubular member to be expanded to the open structure.

33. The contraceptive device of claim 27 wherein the tubular member comprises braided filaments configured to allow the tubular member to be expanded to the open structure.

34. A contraceptive device for deployment in a female patient's fallopian tube, comprising: a) A tubular body which has a longitudinal axis, which at least in part is radially expandable about the longitudinal axis within the patient's fallopian tube from a first tubular configuration to a second tubular configuration having larger transverse dimensions than the first tubular configuration to facilitate securing a least a portion of the expanded tubular body to a wall portion defining at least in part a lumen of the female patient's fallopian tube and which has an open structure in the expanded configuration facilitating ingrowth of tissue cells; and b) a member within the radially expandable tubular body which is configured for tissue growth.

35. A sterilization device occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising: a) a tubular member having a first end, a second end, and a lumen extending therein, the tubular member at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration; and b) a mesh member connected to the tubular member, the mesh member permeable and receiving tissue ingrowth therein so as to occlude the reproductive body lumen.

→ 36. A contraceptive device installed within a lumen of the patient's reproductive system, comprising a) a tubular member having a first end, a second end, and a lumen extending therein, and having at least a portion thereof which is secured to a body wall portion defining at least in part the lumen of the patient's reproductive system; and b) an occluding member connected to the tubular member comprising a mesh receiving tissue ingrowth therein, the ingrown mesh occluding the lumen of the patient's reproductive system sufficiently to prevent the passage of reproductive cells therethrough.

37. A contraceptive or sterilization device for occluding a fallopian tube to inhibit conception, the fallopian tube capable of producing ingrowth tissues, the device comprising: a) a tubular structure having a first end, a second end, and a lumen extending therein, the tubular structure expandable within the fallopian tube from a first configuration to a second larger configuration; and b) a tissue ingrowth element connected to the tubular structure, the tissue ingrowth element receiving tissue ingrowth to thereby occlude the fallopian tube.

38. A contraceptive device, comprising a tubular body which has a longitudinal axis, which is at least in part configured to be radially expanded about the longitudinal axis

within a lumen of a patient's reproductive system from a first tubular configuration to a second retained tubular configuration having larger transverse dimensions than the first tubular configuration, which has an open structure in the retained expanded configuration for ingrowth of tissue cells for securing the expanded portion of the tubular body to a wall portion of the patient's reproductive system lumen, and which has a member at least partially within the tubular body which is configured for tissue growth.

39. The contraceptive device of claim 38 wherein the member at least partially within the tubular body promotes tissue growth including an inflammatory response.

40. A contraceptive device, comprising a) a tubular body which has a longitudinal axis, which is at least in part configured to be radially expanded about the longitudinal axis within a lumen of a patient's reproductive system from a first tubular configuration to a second retained tubular configuration having larger transverse dimensions than the first tubular configuration to facilitate securing at least a portion of the tubular body to a wall portion defining at least in part a lumen of a patient's reproductive system and which has an open structure in the retained expanded configuration facilitating the ingrowth of tissue cells; and b) a member at least partially within the expandable tubular body which is configured for tissue growth.

41. The contraceptive device of claim 38 wherein the tubular member comprises a tube having a pattern of slots.

42. The contraceptive device of claim 38 wherein the tubular member is formed of a helical wire.

43. The contraceptive device of claim 38 wherein the tubular member comprises braided filaments.

44. The contraceptive device of claim 40 wherein the tubular member comprises a tube having a pattern of slots.

45. The contraceptive device of claim 40 wherein the tubular member is formed of a helical wire.

46. The contraceptive device of claim 40 wherein the tubular member comprises braided filaments.

47. A contraceptive device for deployment in a female patient's fallopian tube, comprising: a) A tubular body which has a longitudinal axis, which at least in part is configured to be radially expanded about the longitudinal axis within the patient's fallopian tube from a first tubular configuration to a retained second tubular configuration having larger transverse dimensions than the first tubular configuration to facilitate securing at least a portion of the expanded tubular body to a wall portion

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defining at least in part a lumen of the female patient's fallopian tube and which has an open structure in the retained expanded configuration facilitating ingrowth of tissue cells; and b) a member at least in part within the tubular body which is configured for tissue growth.

48. The contraceptive device of claim 38 wherein the tubular body is configured at least in part to retain substantially the second tubular configuration for sufficient time for tissue growth to epithelialize at least an expanded portion of the tubular body.

49. The contraceptive device of claim 40 wherein the tubular body is configured to retain substantially the second tubular configuration at least in part for sufficient time for tissue growth to epithelialize at least an expanded portion of the tubular body.

50. The contraceptive device of claim 38 wherein at least part of the tubular body is configured to have outer transverse dimensions in the expanded second configuration which substantially conform to inner transverse dimensions of the patient's reproductive lumen at an expansion site in the reproductive lumen.

51. The contraceptive device of claim 40 wherein at least part of the tubular body is configured to have outer transverse dimensions in the expanded second configuration which substantially conform to inner transverse dimensions of the patient's reproductive lumen at an expansion site in the reproductive lumen.

52. The contraceptive device of claim 47 wherein the tubular body is configured at least in part to retain substantially the second tubular configuration for sufficient time for tissue growth to epithelialize at least an expanded portion of the tubular body.

53. The contraceptive device of claim 47 wherein the tubular body is configured to substantially conform to the inner transverse dimensions of the patient's fallopian tube in the second tubular configuration and to at least in part to retain substantially the second tubular configuration for sufficient time for tissue growth to epithelialize at least an expanded portion of the tubular body.

54. A method of human contraception comprising a) providing a contraceptive device comprising a tubular body and a member which is configured for tissue growth which is disposed at least partially within the tubular body; b) inserting within a lumen of a patient's reproductive system at least a portion of the contraceptive device including at least part of the tubular body and at least part of the tissue growth member; and c) within a region of the patient's reproductive lumen, radially expanding at least a tubular portion of the tubular body about a longitudinal axis from a first configuration to a second configuration having outer transverse dimensions which are larger than outer transverse

dimensions in the first configuration and which substantially conform to the inner transverse dimensions of the patient's reproductive lumen in the region where the tubular portion is expanded.

55. The method of claim 54 wherein occlusion of the reproductive lumen is facilitated by tissue growth promoted by the tissue growth member.

56. The method of claim 54 wherein the tissue growth member includes an inflammatory response.

57. The method of claim 54 wherein contraception is aided by a contraceptive agent associated with the device.

58. The method of claim 54 wherein the tubular portion is expanded at least partially by self-expanding.

59. The method of claim 54 wherein the step of inserting at least a portion of the contraceptive device within the patient's reproductive lumen further comprises using a catheter to introduce at least the portion of the contraceptive device into the reproductive lumen.

60. The method of claim 54 wherein the expanded tubular portion is retained substantially in the second configuration within the patient's reproductive lumen.

61. The method of claim 54 wherein at least part of the expanded tubular portion of the tubular body is secured by tissue ingrowth to a wall of the patient's reproductive lumen.

62. The method of claim 54 wherein tissue growth epithelializes the expanded tubular portion of the tubular body and at least a portion of the tissue growth member within the patient's reproductive lumen.

63. The method of claim 54 wherein the contraceptive device is secured to a portion of a wall forming the patient's reproductive lumen.

64. The method of claim 62 wherein the contraceptive device is secured to a portion of a wall forming the patient's reproductive lumen by epithelializing the expanded tubular portion of the tubular body within the reproductive lumen.

65. The method of claim 54 wherein the radial expansion of the tubular portion of the tubular member to the second larger configuration secures at least the expanded tubular portion of the tubular body at an expansion site within the patient's reproductive lumen.

66. A human contraceptive device comprising a) a tubular body which has a longitudinal axis, which has at least a tubular portion that is configured to be radially expanded within a lumen of a patient's reproductive system about the longitudinal axis from a first tubular configuration to a second tubular configuration having outer transverse dimensions which are larger than outer transverse dimensions in the first configuration and which substantially conform to inner transverse dimensions of the patient's reproductive lumen at an expansion site therein; and b) a member which is configured for tissue growth and which is disposed at least partially within the tubular body.

67. The contraceptive device of claim 66 wherein the tubular portion is configured to have an open structure in the second tubular configuration.

68. The contraceptive device of claim 67 wherein the tubular portion is configured to be retained in the expanded configuration.

69. The contraceptive device of claim 66 wherein the tubular portion is configured to have an open structure in the expanded second configuration.

70. The contraceptive device of claim 67 wherein the tubular body is selected from the group consisting of a tube having a pattern of slots, a helical wire, and braided filaments.

71. The contraceptive device of claim 66 wherein the tubular body is configured to promote tissue growth including an inflammatory response.

72. The contraceptive device of claim 66 including a deliverable contraceptive agent.

73. The contraceptive device of claim 66 wherein the tissue growth member is configured to support tissue growth that contributes to occlusion of the reproductive lumen.

74. The contraceptive device of claim 66 wherein the tubular portion of the tubular body is at least partially self-expanding.

75. The contraceptive device of claim 66 wherein at least a portion thereof is configured to be secured by tissue ingrowth to a wall of the patient's reproductive lumen.

76. The contraceptive device of claim 66 wherein the tubular portion of the tubular body and the tissue growth member are configured to provoke tissue growth that epithelializes the expanded tubular portion of the tubular body and at least a portion of the tissue growth member within the patient's reproductive lumen to substantially occlude the reproductive lumen.

77. The contraceptive device of claim 66 wherein at least part of the tubular body is configured to be secured to a portion of a wall forming the patient's reproductive lumen.

78. The contraceptive device of claim 66 wherein the tubular portion of the tubular body is configured to be secured to a portion of a wall forming the patient's reproductive lumen by epithelialization thereof.

79. The contraceptive device of claim 66 wherein the tubular portion of the tubular body is configured to be secured within the patient's reproductive lumen upon expansion to the second configuration.

80. A method of human contraception comprising a) providing a contraceptive device comprising a tubular body which has a longitudinal axis, which at least in part is configured to be radially expanded about the longitudinal axis within a patient's reproductive lumen from a first tubular configuration to a second tubular configuration having larger transverse dimensions than the first tubular configuration to facilitate securing at least a portion of the expanded tubular body to a wall portion defining at least in part the patient's lumen, and which has an open structure in the expanded configuration facilitating ingrowth of tissue cells; b) inserting within a lumen of a patient's reproductive system at least a portion of the contraceptive device including at least part of the tubular body; and c) within a region of the patient's reproductive lumen, radially expanding at least a tubular portion of the tubular body about the longitudinal axis from the first configuration to the second configuration which substantially conforms to inner transverse dimensions of the patient's reproductive lumen in the region where the tubular portion is expanded and which facilitates tissue growth that epithelializes the expanded tubular portion of the tubular body within the patient's reproductive lumen.

81. A contraceptive device, comprising a) a body expandable within a lumen of a patient's reproductive system from a first tubular configuration to a second tubular configuration, the second tubular configuration having a larger cross-sectional profile than the first tubular configuration relative to an axis of the contraceptive device to facilitate securing at least a portion of the body to a wall portion defining at least in part a lumen of a patient's reproductive system, the body comprising a helical coil and allowing the ingrowth of tissue; b) a material disposed at least in part within the expandable body so as to incite tissue in-growth.